The Joint Standing Committee of Appropriations and Financial Affairs
Testimony from Dr. David Shoemaker, Shoemaker Regulatory Consulting, LLC

In Support of LD 416

LD 416
An Act to Authorize a General Fund Bond Issue for Research and Development and Commercialization

24 April 2023

Senator Rotundo, Representative Sachs, and members of the Joint Standing Committee on Appropriations and Financial Affairs:

My name is David Shoemaker and I am the sole proprietor of Shoemaker Regulatory Consulting, LLC, located in Portland, Maine. I am here today to present testimony in support of LD 416.

I am a PhD microbiologist and I spent 21 years on active duty in the U.S. Army Medical Research and Materiel Command helping develop medical products for the Department of Defense. My specific area of expertise was in helping DoD partners navigate the complex pathway of getting biotech products through the FDA approval process. LD 416 would provide critical funding that is sorely needed by current and future biotech startups in Maine to help them successfully get their products through the FDA and bring good-paying tech jobs to Maine.

I moved to Maine after retiring from the Army and over the past year have been a mentor to the Dirigo Labs Accelerator in Waterville, as well as the Roux Institute, where I have been helping educate and guide biotech startup companies with respect to the FDA regulations. The financial burden of complying with FDA regulations is almost always underappreciated by funding organizations. Even with relatively simple FDA-regulated medical devices, it usually takes at least a 6-figure investment in order to comply with the basic FDA requirements.

Take for example Hussey Medical from Waterville, which was founded in 2019 by Bob Hussey and his sons Dan and Dave. They are developing a product that will significantly enhance the quality of life for patients that have an ostomy. However, the development of their product is at a virtual standstill due to lack of funding required to fully comply with the FDA regulations.

Similarly, Heather Desjardins from Winthrop founded her company, i-Tell Alert in 2018, and she is developing an accessory product for mechanical walkers that will help prevent falls and subsequent injuries in our elderly population. She also is at a virtual standstill in her product development due to a lack of funds to support the FDA regulatory requirements.

Last month, before I even became aware of LD416, I wrote a white paper on four key things we can do in the state of Maine to promote our biotech industry. One of these four things was to provide more funding to biotech companies specifically to support what I call the "unseen

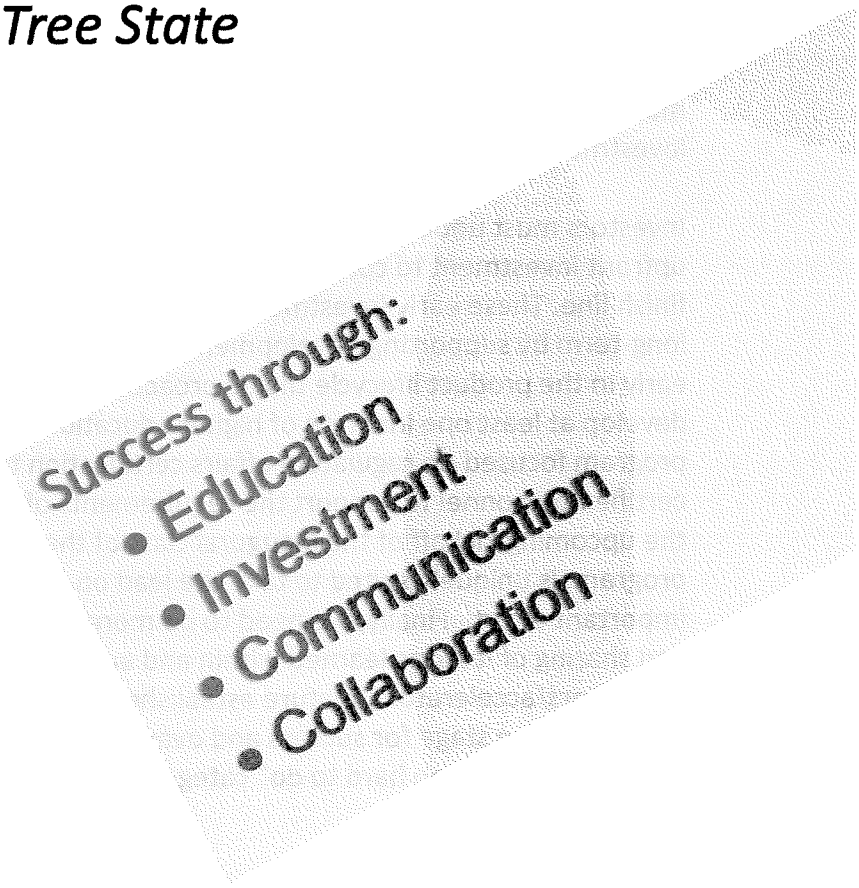
infrastructure" required to comply with the FDA regulations and successfully bring biotech products to market. I have attached a copy of the white paper to my testimony.

For these reasons, I urge you to support LD416 so that together we can help make Maine a world-class biotech nexus. Thank you for the opportunity to testify today.

Sincerely,

David Shoemaker, Ph.D.
LTC (ret), U.S. Army
Shoemaker Regulatory Consulting, LLC
Email: drs12345@gmail.com

Investment in Maine Medical Device Startups:
De-risking Investment in, and Encouraging Development of, a Successful Medical Device Industry in the Pine Tree State



Date Prepared:
31 March 2023

Prepared by:
Dave Shoemaker, Ph.D.
LTC (ret), U.S. Army
Shoemaker Regulatory Consulting, LLC
Email: drs12345@gmail.com
Phone: 301-471-1290

Approved for release 31 MAR 2023

Introduction

There is a relative paucity of medical device companies in Maine. Only 40 registrations representing 37 different companies are listed in the FDA database for the state of Maine. I have provided this list of companies in a rather lengthy 9-page attachment to this document, not because I expect you to read it line-by-line, but rather to provide you a single-source listing of Maine FDA-regulated medical device companies to refer back to in the future if the need arises. These companies are involved in the manufacturing, relabeling, or repackaging of over 250 FDA-regulated medical devices, ranging from tongue depressors and dental floss, to COVID tests and neurological stereotaxic instruments. Opportunities exist to expand the medical device environment in Maine to make it a world-class biotech nexus, *provided* some significant steps are taken and investments made to assist this specialized and regulatory-heavy industry.

Investors must understand that medical device companies require significant early upfront investment to comply with FDA regulations just to get their product to the FDA finish line. These early investments should actually *decrease* overall costs in the mid-to long-term by supporting development of a professional regulatory development plan early in the product lifecycle that is proactive, compliant, and efficient. Maine must develop at least one institute of higher education that offers a Master's or certificate program focused on regulatory affairs certification to help develop in-state regulatory-certified personnel to support the requirements of this industry. The Roux Institute, with the upcoming kickoff of the inaugural class of the Healthcare Founder Residency program, is uniquely suited to take the lead on this complementary but critically important effort. Finally, we need to do more to encourage and assist communications and sharing of lessons-learned within and among medical device startups, startup incubators/accelerators, mature established companies, and the academic community, to help set the stage for success and overcome any mindset that developing medical devices is in the "too hard to do" category.

The Problem

Over the past 12 months I have been a volunteer mentor to the Dirigo Labs Accelerator (Waterville, ME) that was established in 2022. During this time I have come across two Maine startup companies, each established 4 years previously, that were developing FDA-regulated products. Quite unfortunately, after 4 years neither of these two companies realized that the product they were developing was regulated by the FDA, and apparently neither did the individuals and institutions that funded these 2 companies. Had either of these two companies started to market their product without satisfying the FDA regulations, they would have been subject to FDA warning letters and potentially shut down by the FDA for selling misbranded products. I have mentored a third company that correctly identified early on that their device was regulated by the

FDA, but lacked early access to affordable expert regulatory assistance, thereby resulting in avoidable expenses and an increased product development timeline. The purpose of this paper is to discuss some challenges specific to the development of FDA-regulated medical devices, and some possible approaches for addressing these challenges in order to help bring Maine to the forefront as a nationwide leader in medical device development.

Case Study: Company A

At the time I met Company A it consisted of about 8 full-time employees, had received approximately $3.5M in funding, and was preparing to launch their product within weeks. The company had received considerable positive publicity over the previous couple of years and had been recognized by a variety of entrepreneur publications and awards. A senior individual from the company gave a 20-minute talk at an event I attended in June 2022. During the presentation it was immediately apparent to me that their product was a medical device subject to the FDA regulations, and I asked him what was the company's FDA regulatory strategy. The reply boiled down to *"...our lawyer told us it is just software and not regulated by the FDA..."* Software absolutely *CAN* be an FDA-regulated medical device, and there have been hundreds, perhaps thousands, of software applications, including mobile medical apps and artificial intelligence products, cleared by the FDA. For example, do you have an Apple watch? The electrocardiogram function of the Apple watch is an FDA-regulated medical device that was cleared by the FDA in 2021. The problem is that most people, lawyers included, do not know what FDA-regulated medical devices are, and therefore do not know what questions to ask and what to look for. This naivety occurs not only amongst developers of medical devices, but also amongst the individuals and organizations that fund the development of these products. I readily identified Company A's product as an FDA-regulated medical device and was able to help the company develop a regulatory pathway to meet the FDA requirements. Importantly, Company A was able to obtain funding required to hire additional regulatory consultants to help them develop a Quality System compliant with FDA regulations, and to meet all other FDA requirements. For other startup companies, this late identification that they had an FDA-regulated device could have been a death knell. Company A was fortunate; their marketing launch timeline was delayed a few months, but ultimately successful.

Case Study: Company B

At the time I met Company B, it had also been founded 4 years previously and consisted soley of the CEO who was working to finalize the product design. When I asked about the Company's regulatory strategy, I was told *"....oh, I asked a lawyer who told me it was not an FDA medical device..."* This was incorrect; the intended use of Company B's product made it a medical device subject to FDA regulations. It should be noted that

there are very few lawyers with the breadth and depth of experience needed to provide proper and accurate advice on FDA regulatory issues. It is essential that medical device startups get advice from a true regulatory professional expert that is experienced and well-versed in the FDA regulations. I educated the CEO on why their product was a medical device, and am currently working with them to develop an appropriate FDA regulatory pathway and plan that will lead to success. However, significant hurdles exist in identifying funding sources to: 1) support establishment of an FDA-compliant quality system that must be in place prior to FDA clearance/approval, 2) conduct clinical evaluations, 3) put together a FDA premarket notification package, and 4) pay FDA submission fees. Additional funding, likely in the low- to mid-six figures will be needed to successfully meet the FDA requirements and bring this product to market. While there is interest among potential users of this device, potential interest from investors has been lukewarm due in part to lack of understanding of what it takes to get a device successfully through the FDA process, and the amount of funding to support that process.

Case Study: Company C

Company C is currently a 3-person company that did successfully identify early in their product development effort that they had an FDA-regulated medical device. However, they did not realize they needed advice from an expert in regulatory affairs at such an early stage of their company in order to enable the most efficient and cost-effective development of their product. As a result, even though they were still several years away from being ready to go to market, they promptly applied to get their company registered with the FDA and paid the $5,500 fee to FDA. This was totally unnecessary; registering your company with the FDA is not required until *after* your product has been cleared/approved by the FDA and you are ready to go to market. Company C therefore wasted $5,500 because they did not understand the FDA process. Furthermore, they were planning a clinical trial at a well-known Boston hospital using a version of their device that had not been manufactured in accordance with the FDA Quality System Regulations, and likely would not be the finalized version of their device that would go to market. Therefore the proposed clinical trial, while perhaps providing some early usability data for the device, would not have been acceptable to the FDA for evidence of safety and effectiveness since it was not intended to be conducted using the finalized version of the device. Clinical trials of investigational medical devices are expensive and resource-intensive and should be planned to generate data that can directly support an FDA premarket submission. Lastly, and frankly most importantly, Company C did not know how to go about, or even where to find, assistance from regulatory affair experts who could help them. I am currently mentoring the company to develop a regulatory strategy and pathway forward, but Company C needs more regulatory support than I can provide. They obtained a quote of $106K from a large, well-known and well-respected

regulatory support company for the development and execution of a comprehensive FDA regulatory plan. Note that this quote did not include support to establish an FDA-compliant Quality System, which would be an additional significant cost. As with Company B, Company C is currently struggling to identify investors willing to come to the table with funding to support the regulatory requirements for their device. Without this support Company C will fail.

What can we learn from this small sample size of just 3 startup medical device companies here in Maine?

Issue 1: Education

It is quite evident that the startup community needs to be educated on what an FDA-regulated medical device is so that early identification of such products can be made. Early identification is absolutely imperative (but underappreciated) so that an appropriate regulatory plan can be developed early, and appropriate funding is identified and obtained to get through the FDA process. Education on the regulatory requirements of medical devices should be done within the startup entrepreneur community and the investment communities that fund such ventures. Institutional Review Boards (IRB's) at hospitals and universities should also receive training since proposed clinical studies that they review oftentimes utilize investigational medical devices which must also comply with FDA regulations. Education can readily be addressed by having regulatory professionals develop short, concise, and easily understood training packets on how to identify if a product is an FDA-regulated medical device. Ideally this type of training can be given in-person or via an online forum whereby the audience has the opportunity to ask questions. In addition to these types of training, it is critically important that the investment, development, and IRB communities have ready and easy access to regulatory experts with significant medical device expertise so that any questions can be quickly and accurately answered.

In addition to education, organizations that provide funding for startups such as angel and venture capital funders, and public/private partnerships such as the Maine Technological Institute, should have baseline reviews of their entire portfolio conducted by a qualified regulatory professional expert. This will help ensure that any medical device startup efforts not previously identified as having an FDA-regulated product are identified. Additional planning for regulatory support for these efforts can then be done, thus enhancing opportunity for successful business development. Funding organizations should implement processes to ensure that every new business proposal received is given a thorough regulatory review to avoid instances such as Company A and B getting 4 years into the developmental pathway before realizing their product must comply with the FDA regulations in order to be marketed.

Funding organizations need quick and ready access to regulatory professional experts when questions arise. The pool of regulatory professionals well-versed in FDA medical device regulations in Maine is severely limited; if sufficient organic support within the state cannot be identified, outside contract research organizations with expertise in this area should be identified and funding provided to ensure that investment in potential medical device startups is optimized for success.

Given that the extremely small pool of medical device regulatory professionals in Maine, investment should be made to grow this capability within the state. One straightforward and direct way to do this is to encourage institutes of higher learning to offer a master's degree program or certificate program in regulatory science. Biotech and regulatory science programs go hand-in-hand; you must have good scientists to develop the initial technology, but you cannot successfully get FDA-regulated biotech products to market without having the regulatory professionals to help develop and guide the efforts through the FDA process. The Roux Institute would appear to be an ideal candidate to initiate a regulatory science program. Discussions should be initiated to seriously consider this proposal, and to identify other institutions that might also be able to successfully implement such a degree or certificate program.

Issue 2: Investment

Startup companies that intend to develop an FDA-regulated product face a huge disadvantage compared to companies developing non-regulated FDA products. Satisfying FDA requirements for medical devices is very expensive. Even for the simplest medical devices it will take a 6-figure investment for a new startup company, at minimum, to satisfy the baseline FDA regulatory requirements to bring it to market. Almost all medical device startup companies, and many if not most investors, drastically underestimate what resources are required to get through the FDA process. Getting a medical device "through the FDA" involves much more than just submitting a 510(k) application to the FDA. Prior to submitting any marketing applications to the FDA, medical device companies must establish, and maintain, a Quality System that meets the requirements of 21 CFR 820. If clinical studies must be done to support an FDA application, they must be done under a protocol that has been approved by an IRB, must follow the Investigational Device Exemption regulations in 21 CFR 812, and must be carried out using the finalized version of their medical device that has been manufactured under their established Quality System. Too often investors supporting medical device development believe that the FDA process happens only at the end of product development, right before marketing. That is NOT the case; the FDA regulatory process begins, or *should* begin, as soon as the device is identified as being a medical device. Organizations providing investment into medical device startups should fully

understand upfront the regulatory costs entailed to get a successful return on their investment. If a decision is made to invest they should do so with the understanding that skimping on investment in regulatory support substantially increases the risk of a poor outcome.

Issue 3: Communication and Collaboration

Synergy in a particular industry is fostered through free-flow of information among individuals that are excited about what they do. Establishing good communications and collaborations between and among startup companies and already-established companies is essential to support building the informal networks that are the foundation of tech hubs such as Boston's biotech corridor and Silicon Valley. If as a state we want to promote Maine to be a leader in the medical device industry, we need to work to encourage synergy in this industry. The good news is that this is already beginning to happen; the Roux Institute's Future of Healthcare Founder Residency Program is bringing 10 healthcare startup companies to Portland for an intensive year-long program. While not all 10 companies will develop FDA-regulated products, some of them will. We need to capitalize on this by providing opportunities for these startups to network with other startup efforts around the state. There also needs to be a deliberate and concerted effort to facilitate interactions between medical device startups and the 37 established Maine companies listed in Attachment 1; after all, these 37 "veteran" companies have already made it through the gauntlet to get FDA's blessing. They understand what it takes to establish a rigorous Quality System and to generate the necessary data that goes into a premarket submission to the FDA. Given the scarcity of regulatory and quality affairs expertise within Maine, these companies hold a wealth of knowledge and lessons learned. Engaging with these companies could result in a huge positive boost to the medical device community in Maine.

Final thoughts

These are exciting times to be involved in Maine biotech! It is encouraging to see that various groups around the state are supporting the industry. I spent my career in the Army helping develop FDA-regulated medical products and worked with various government agencies and labs, major universities, medical centers, and many startup companies. I have seen not only many failures, but many successes as well. The organizations that were successful did not stick their head in the sand when told that their product was regulated by the FDA (and trust me, there were those such as Theranos that did!). Rather, they sought out the appropriate expertise that they needed to navigate the "black box" of the FDA to ensure that they were able to develop a safe and effective product that satisfied the FDA regulations. My passion is to help ensure that here in Maine we do everything we can to help our biotech startups be successful.

About the author: *Dr. Shoemaker spent 21 years on active duty in the U.S. Army helping develop medical products for the warfighter. He was assigned full-time at the FDA for a year to learn what it takes to get the FDA "seal of approval" for medical devices, and during subsequent assignments advised and assisted the DoD on hundreds of different FDA-regulated products. One of the most memorable projects he worked on is described in chapter 10 ("Who is LTC Shoemaker?") of John Careyrou's book Bad Blood.*

ATTACHMENT 1: FDA-registered medical device companies in Maine as of 26 March 2023, and their listed products.
From https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Establishment Name	Device Listing	FDA Registration #	Current Registration
ABBOTT DIAGNOSTICS SCARBOROUGH, INC.		1221359	2023
	Plasmodium Spp. Detection Reagents - BinaxNow Malaria Test		Manufacturer
	Antigen, Cf (Including Cf Controls), Respiratory Syncytial Virus - Alere BinaxNOW RSV Card; BinaxNOW RSV Card; BinaxNOW RSV Test		Manufacturer
	Antisera, All Groups, Streptococcus Spp. - Alere BinaxNOW Streptococcus Pneumoniae Antigen Card; BinaxNOW Streptococcus Pneumoniae Antigen Card; BinaxNOW Streptococcus Pneumoniae Test		Manufacturer
	Legionella, Spp., Elisa - Legionella Urinary Antigen Enzyme Immunoassay Kit		Manufacturer
	Antisera, All Groups, Streptococcus Spp. - Alere BinaxNOW Strep A Card; BinaxNow Strep A Test		Manufacturer
	(41 Listings in Total)		
Abbott Diagnostics Scarborough, Inc.		3017662853	2023
	Coronavirus Antigen Detection Test System. - BinaxNOW COVID-19 Ag 2 Card (EUA210275); BinaxNOW COVID-19 Ag Card (EUA202537); BinaxNOW COVID-19 Ag Card Home Test (EUA203107); BinaxNOW COVID-19 Antigen Self-Test (EUA210264); Panbio™ COVID-19 Antigen Self-Test (Abbott Diagnostics Korea Inc.)		Manufacturer
	Glucose-6-Phosphate Dehydrogenase (Erythrocytic), Screening - BinaxNow G6PD Test		Manufacturer
	Devices Detecting Influenza A, B, And C Virus Antigens - Alere BinaxNOW Influenza A & B Card 2; Alere Reader; BinaxNOW Influenza A & B Card 2; DIGIVAL		Manufacturer
	Antisera, All Groups, Streptococcus Spp. - Alere BinaxNOW Strep A Card; BinaxNow Strep A Test		Manufacturer
	Plasmodium Spp. Detection Reagents - BinaxNow Malaria Test		Manufacturer
	(10 Listings in Total)		
ACCELERA, INC.		3023788925	2023
	Piezo-Electric Stimulator For Relief Of Mosquito Bite Itch - SR100		Specification Developer
ACME-MONACO CORP.		1222301	2023
	Bracket, Metal, Orthodontic - MULTIPLE PRODUCTS		Contract Manufacturer; Manufacturer

Establishment Name	Device Listing	FDA Registration #	Current Registration
	Wire, Orthodontic - MULTIPLE PRODUCTS		Contract Manufacturer; Manufacturer
	Spring, Orthodontic - MULTIPLE PRODUCTS		Contract Manufacturer; Manufacturer
	Clamp, Wire, Orthodontic - MULTIPLE PRODUCTS		Contract Manufacturer; Manufacturer
	Wire, Guide, Catheter - Multiple *(6 Listings in Total)*		Contract Manufacturer; Manufacturer
ARTEL, INC.		1221020	2023
	Colorimeter, Photometer, Spectrophotometer For Clinical Use		Contract Manufacturer
AUSTIN MEDICAL PRODUCTS, INC.		1220581	2023
	Protector, Ostomy - AMPatch		Manufacturer
CASCO BAY MOLDING		3003270419	2023
	Cup, Menstrual - Agua Cup; Aria Cup; BelaBud; Best, Periodt.; BLOOM Cup; Casco Cup; Casco Disc; Cheremi Maka; Cherry Cup; DOT FEMININE; Elacup; Elicole LLC; Ennie Cup; Eva Copa Menstrual; EVE Cup; FitCup By BeGirl; FLOW Fem; HappyCup; Hercup Menstrual Cup; Herday; Inacup; LePinkky; LifeCup; Lincup By Lintimate; LOLA Menstrual Cup; Luafem By Importop; Lunacup; Mahina Cup By Sacred Cycle; Miaa Cup; My Box Shop; My Menstrual Cup; MyEverCup; OVACup; The Vampire Shot Glass; Tricup Menstrual Cup; Venus Cup; Vera Cup; Wa Cup By Wa Collective		Contract Manufacturer; Manufacturer
	Shield, Nipple - Back To Mom Nipple Shield Weaning Kit		Manufacturer
	Ring, Teething, Non-Fluid Filled - Chewy Tubes; Opulent Global Products		Manufacturer
CORNING INC., LIFE SCIENCES		1218905	2023

Establishment Name	Device Listing	FDA Registration #	Current Registration
	Flask, Tissue Culture - CellCube Systems And Accessories, Various Styles And Sizes; CellSTACK Culture Chambers And Accesories, Various Styles And Sizes;; Corning Erlenmeyer Flasks, Various Sizes;; Corning PureCoat RLaminin-521 Cultureware; Various Sizes; Falcon MultiFlasks, Various Styles Greater Than 100 Square Cm Surface Area; Falcon, Costar And Corning CELLBIND Cell Culture Flasks Greater Than 100 Square Cm Surface Area; HYPERFlasks And HYPERStack Vessels And Accessories; Various Styles And Sizes; Primaria Flasks Greater Than 100 Square Cm Surface Area. PureCoat Flasks Various Sizes.; Synthemax Flasks Sizes Greater Than 100 Square Cm Surface Area		Manufacturer
	Dish, Tissue Culture - Custom Transwell Permeable Supports > 100 Cm2; PureCoat Cell Culture Plates And Dishes, Various Styles And Sizes; Tissue Culture Dish And BioAssay Dish		Manufacturer
	Spinner System, Cell Culture - Corning Disposable Spinner Flasks		Manufacturer
	System, Suspension, Cell Culture - Corning Polystyrene Microcarrier Beads, Corning Synthemax Microcarrier Beads		Manufacturer
	Bottle, Roller, Tissue Culture - Corning And Custom Roller Bottles And Accessories; Corning CellBIND Roller Bottles And Accessories;		Manufacturer
	(7 Listings In Total)		
Courtney Bed, Inc		3006015254	2023
	Bed, Manual - COURTNEY BED		Manufacturer
DENTAL LACE INC.		3014045831	2023
	Floss, Dental - Dental Lace		Repackager/Relabeler
	Toothbrush, Manual - Dental Lace		Repackager/Relabeler
ENERCON TECHNOLOGIES		3003018722	2023
	Camera, Ophthalmic, Ac-Powered		Contract Manufacturer
	Choledochoscope And Accessories, Flexible/Rigid - SpyGlass DS Digital Controller		Contract Manufacturer
	Camera, Surgical And Accessories - SpyGlass DS Digital Controller		Contract Manufacturer
	Led Light Source - SpyGlass DS Digital Controller		Contract Manufacturer
	Respiratory Virus Panel Nucleic Acid Assay System - Groups A, C And G Beta-Hemolytic Streptococcus Nucleic Acid Amplification System; Influenza A And Influenza B Multiplex Nucleic Acid Assay; Real Time Nucleic Acid Amplification System; Respiratory Virus Panel Nucleic Acid Assay System		Contract Manufacturer
	(25 Listings In Total)		

Establishment Name	Device Listing	FDA Registration #	Current Registration
FHC, INC.		3002250546	2023
	Neurological Stereotaxic Instrument - MICROTARGETING DRIVE SYSTEM		Manufacturer
	Neurological Stereotaxic Instrument - MICROTARGETING DRIVE SYSTEM		Manufacturer
	Electrode, Depth - MICROTARGETING GUIDELINE 4000		Manufacturer
	Electrode, Depth - Guideline System 3000		Manufacturer
	Neurological Stereotaxic Instrument - MP-1 Micropositioner		Manufacturer
	(19 Listings in Total)		
GEIGER		1223149	2023
INSIGHTFUL PRODUCTS		3005526310	2023
	Orthosis, Foot Drop - Step-Smart, Blaze		Manufacturer
KINOTEK		3023517494	2023
	Interactive Rehabilitation Exercise Device, Prescription Use - MSK Health Platform		Manufacturer; Complaint File Establishment
LGC Clinical Diagnostics, Inc.		1226774	2023
	Multi-Analyte Controls, All Kinds (Assayed) - MSC Chem 4 Calibration Verification Test Set; VALIDATE Chem 2 Calibration Verification Test Set; Validate Chem 4 Product Code 104ab		Manufacturer
	Plasma, Coagulation Control - Validate Heparin Se Calibration Verification /Linearity Kit, Product Code 903se; Validate Heparin St Calibration Verification /Linearity Kit		Manufacturer
	Plasma, Fibrinogen Control - Plasma, Fibrinogen Control; Validate Fibrinogen Il Calibration Verification/Linearity Test Kit, Product Code 904il; Validate Fibrinogen Se Calibration Verification/Linearity Test Kit, Product Code 904se; Validate Fibrinogen St Calibration Verification/Linearity Test Kit, Product Code 904st		Manufacturer

Establishment Name	Device Listing	FDA Registration #	Current Registration
	Multi-Analyte Controls Unassayed - ACCURUN® 120 HAV IgG Positive Control; ACCURUN® 121 HAV IgM Positive Control; ACCURUN® 130 Lyme IgG Positive Control; ACCURUN® 132 Lyme IgM Positive Control; Validate Ferritin Unassayed Calibration Verification/Linearity Test Solution, Product Code 307; Validate Fertility 1 Unassayed Calibration Verification/Linearity Test Kit Product Code 502re; Validate Fertility 2 Unassayed Calibration Verification/Linearity Test Kit Product Code 504re; Validate HbA1c Unassayed Calibration Verification/Linearity Test Kit, Product Code 605; Validate Heparin Se Calibration Verification /Linearity Kit, Product Code 903se; Validate SP2 Unassayed Calibration Verification/Linearity Test Kit, Product Code 602bc; Validate SP2 Unassayed Calibration Verification/Linearity Test Kit, Product Code 602re; Validate SP2 Unassayed Calibration Verification/Linearity Test Solution, Product Code 602; Validate Tumor Markers Unassayed Calibration Verification/Linearity Test Kit, Product Code 407; Validate Tumor Markers Unassayed Calibration Verification/Linearity Test Kit, Product Code 407sa; Validate Whole Blood Glucose Unassayed Calibration Verification/Linearity Test Kit, Product Code 607		Manufacturer
	Multi-Analyte Controls, All Kinds (Assayed) - VALIDATE Anemia Calibration Verification/Linearity Test Kit, Product Code 305		Manufacturer
	(36 Listings in Total)		
LIGHTHOUSE IMAGING LLC		1226499	2023
	Accessories, Photographic, For Endoscope (Exclude Light Sources) - Endoscopic Video Coupler		Contract Manufacturer; Manufacturer
	Endoscope, Rigid - Inside View		Contract Manufacturer; Manufacturer
	Laryngoscope, Rigid - King Vision Video Laryngoscope		Contract Manufacturer
LONZA ROCKLAND, INC.		1219614	2023
	Apparatus, Electrophoresis, For Clinical Use - Lonza		Manufacturer
MAINE BIOTECHNOLOGY SERVICES, INC.		1226802	2023
	Reagents, Specific, Analyte - MAB105P; MAB106P; MAB107P		Manufacturer
MAINE MOLECULAR QUALITY CONTROLS, INC.		3005959679	2023

Establishment Name	Device Listing	FDA Registration #	Current Registration
	Quality Control Material, Genetics, Dna - INTROL CF PANEL I CONTROL		Manufacturer
	Quality Control Material, Genetics, Dna - INTROL CF Panel I Control V.02		Manufacturer
	Assayed External Control Material For Microbiology Nucleic Acid Amplification (Nat) Assays - FilmArray Pneumonia/Pneumoniaplus Control		Manufacturer
	Quality Control Material, Genetics, Rna - Xpert BCR-ABL IS Panel C130		Manufacturer
	Assayed External Control Material For Microbiology Nucleic Acid Amplification (Nat) Assays - FilmArray Warrior Control Panel M290		Manufacturer
	(9 Listings in Total)		
MAINE OXY-ACETYLENE SUPPLY CO.		1218978	2023
	Gas, Calibration (Specified Concentration) - AEROBIC MIXTURES; ANAEROBIC MIXTURES; BLOOD GASES; LUNG DIFFUSSION		Contract Manufacturer; Manufacturer; Repackager/Relabeler
MICRO DIRECT, INC.		1223858	2023
	Analyzer, Gas, Carbon-Monoxide, Gaseous-Phase - CO Check Pro; CO Screen		Complaint File Establishment
	Gas Chromatograph, Carbon-Monoxide - CO Check Pro; CO Screen		Complaint File Establishment
MOLNLYCKE MANUFACTURING US, LLC		3010099071	2023
	Dressing, Wound, Hydrophilic - ALLDRESS; Exufiber; LYOFOAM Dressings (A, C, T, Extra); LYOFOAM MAX; Melgisorb Plus; Mepilex; Mepilex Border; Mepilex Border Flex; Mepilex Border Flex Lite; Mepilex Border Heel; Mepilex Border Lite; Mepilex Border Post Op; Mepilex Border Sacrum; Mepilex Heel; Mepilex Lite; Mepilex Transfer; Mepilex Up; Mepilex XT; MEPORE; Mepore Film And Pad; Mepore Pro; MESALT; Mesorb; Mestopore; Mextra Superabsorbent		Manufacturer
Molnlycke Manufacturing US, LLC		1225263	2023
	Wound Dressing With Animal-Derived Material(S) - E-Z Derm		Manufacturer
	Bandage, Elastic - Dermafit; Elset; Setopress; Tubifast; Tubigrip; Tubipad		Manufacturer
	Device, Transfer, Patient, Manual - Tortoise Turning And Positioning System		Manufacturer; Repackager/Relabeler

Establishment Name	Device Listing	FDA Registration #	Current Registration
	Protector, Skin Pressure - Static Air Heel Protector; Z-Flex Heel Boot; Z-Flo Fluidized Positioner		Manufacturer
	Lift, Patient, Ac-Powered		Manufacturer
	(6 Listings in Total)		
NEW BALANCE ATHLETICS, INC.		3011093546	2023
	Orthosis, Corrective Shoe - M1080SR4; M1080SS4; M1260SB4; M1340SB2; M1540a24; M1540BG3; M1540BK3; M1540GP3; M1540HB4; M1540MB3; M1540SB2; M860SB4; M860SG4; M940WB2; M990BK4; M990BK5; M990BK6; M990GL4; M990GL5; M990GL6; M990NV4; M990NV5; M990NV6; MW847BK2; MW847BK3; MW847CB4; MW847GY3; MW847LG4; MW847LW4; MW847WT2; MW847WT3; MW928GY2; MW928WM2; W1080BW4; W1080SG4; W1080WP4; W1260GY4; W1260PB4; W1260SB4; W1340SP2; W1540a24; W1540GD3; W1540GR4; W1540SP3; W1540WB2; W860SP4; W860WB4; W940WB2; W990BK4; W990BK5; W990BK6; W990GL4; W990GL5; W990GL6; W990NV4; W990NV5; W990NV6; WW847BK2; WW847BK3; WW847CB4; WW847GR2; WW847GS3; WW847GY3; WW847LG4; WW847LW4; WW847WT2; WW847WT3; WW928NV2; WW928WS2		Manufacturer
NORTHEAST LABORATORY SERVICES, INC.		1210083	2023
	Culture Media, Non-Selective And Differential - PREPARED MICROBIOLO		Contract Manufacturer; Manufacturer
	Culture Media, Selective And Non-Differential - PREPARED MICROBIOLO		Contract Manufacturer; Manufacturer
	Culture Media, Selective Broth - PREPARED MICROBIOLO		Contract Manufacturer; Manufacturer
	Culture Media, General Nutrient Broth - PREPARED MICROBIOLO		Contract Manufacturer; Manufacturer
	Culture Media, Single Biochemical Test - PREPARED MICROBIOLO		Contract Manufacturer; Manufacturer
	(13 Listings in Total)		
OBrien Medical Company LLC		3009648072	2023

Establishment Name	Device Listing	FDA Registration #	Current Registration
	Esthesiometer - PreciseTouch SD		Specification Developer
	Fork, Tuning - ETF 128; ETF Mx		Manufacturer
PHYSICIAN ENGINEERED PRODUCTS, INC.		2183604	2023
	Unit, Neonatal Phototherapy - Bili-Mirror		Manufacturer
	Unit, Neonatal Phototherapy - Ultra Bili Light		Manufacturer
	Unit, Neonatal Phototherapy - Bright Embrace		Manufacturer
PINE TREE ORTHOPEDIC LAB, INC.		3006196605	2023
	Orthosis, Limb Brace - ANDRO AFO; Pine Tree Orthopedic AFO		Contract Manufacturer; Manufacturer; Specification Developer
	Orthosis, Corrective Shoe - Pine Tree Orthopedic AFO		Contract Manufacturer; Manufacturer; Specification Developer
	Orthosis, Foot Drop - Pine Tree Orthopedic AFO		Contract Manufacturer; Manufacturer; Specification Developer
PURITAN MEDICAL PRODUCTS COMPANY LLC		1216735	2023
	Depressor, Tongue, Non-Surgical - Brightwood; Puritan, Pur-Wraps		Manufacturer
	Applicator, Absorbent Tipped, Non-Sterile - Hospital; Puritan, Pur-Wraps		Contract Manufacturer; Manufacturer
	Applicator, Ent - CalgiSwab; Puritan, Pur-Wraps		Contract Manufacturer; Manufacturer
	Spatula, Cervical, Cytological - Cervisoft		Manufacturer
	Applicator, Absorbent Tipped, Sterile - CalgSwab; HydraFlock; PurFlock Ultra; Puritan, Pur-Wraps; PurSwab *(26 Listings in Total)*		Manufacturer
Puritan Medical Products Company, LLC		3018490419	2023
	Applicator, Absorbent Tipped, Non-Sterile - Hospital; Puritan, Pur-Wraps		Manufacturer

Establishment Name	Device Listing	FDA Registration #	Current Registration
	Applicator, Absorbent Tipped, Sterile - CaligSwab; HydraFlock; PurFlock Ultra; Puritan, Pur-Wraps; PurSwab		Manufacturer
PURITAN MEDICAL PRODUCTS, LLC		3017206126	2023
	Applicator, Absorbent Tipped, Sterile - CaligSwab; HydraFlock; PurFlock Ultra; Puritan, Pur-Wraps; PurSwab		Manufacturer
	Applicator, Absorbent Tipped, Non-Sterile - Hospital; Puritan, Pur-Wraps		Manufacturer
SAUNDERS ELECTRONICS		3013919529	2023
	Fork, Tuning - ETF 128; ETF Mx		Contract Manufacturer
	Piezo-Electric Stimulator For Relief Of Mosquito Bite Itch - SR-100		Contract Manufacturer; Manufacturer
SOLSTICE CORPORATION		1221946	2023
	System, X-Ray, Film Marking, Radiographic - XACT		Manufacturer; Repackager/Relabeler
	Applicator, Absorbent Tipped, Non-Sterile - VARIOUS SIZE NON-STERILE A		Repackager/Relabeler; Specification Developer
STERIZIGN PRECISION TECHNOLOGIES		3014409963	2023
	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories - Sterilization Tray, Isto Biologics; SteriZign Signatur Device Cassette And Trays		Manufacturer
STICKMAN DIALYSIS INDUSTRIES INC.		3012706378	2023
	Warmer, Peritoneal Dialysate - Daytripper		Manufacturer
	Catheter, Peritoneal - Tuck-Away Belt		Manufacturer
	Stand, Infusion - Tripod		Manufacturer; Repackager/Relabeler
Sun Diagnostics, LLC		3009672007	2023
	General Purpose Reagent - ASSURANCE Biotin Interferent; Assurance Drug Interference Test Kit; Assurance HAMA Interference Test Kit; Assurance Interference Test Kit; Assurance Interference Test Kit For Endogenous Interferents; Assurance Interference Test Kit For Urine Interferents; Assurance RF Interference Test Kit; LipoSep IP		Manufacturer; Repackager/Relabeler
	Multi-Analyte Controls Unassayed - Fibrinogen QC (FIBQC); GAL3 QC; Leptin QC; LP QC; Lp(A) QC; LP-PLA2 QC; MPO QC; Proinsulin QC (PIQC); TG QC		Manufacturer

Establishment Name		FDA Registration #	Current Registration
	Reagents, Specific, Analyte - N/A		Repackager/Relabeler; Complaint File Establishment
	Research Use Only/Immunology Devices - SunDx Lp(A)-P ELISA; SunDx Rapid Biotin Assay - BTN		Manufacturer; Specification Developer
TAMBRANDS INC.		1219109	2023
	Tampon, Menstrual, Unscented		Manufacturer
	Tampon, Menstrual, Scented, Deodorized		Manufacturer
	Tampon, Menstrual, Unscented		Manufacturer
	Tampon, Menstrual, Unscented		Manufacturer
	Tampon, Menstrual, Unscented		Manufacturer
TOMS OF MAINE, INC.		1218077	2023
	Floss, Dental - DENTAL FLOSS		Repackager/Relabeler; Specification Developer
	Toothbrush, Manual		Repackager/Relabeler; Specification Developer
	Varnish, Cavity - Tom's Of Maine Rapid Relief Sensitive Toothpaste		Manufacturer
TOTAL QUALITY MEDICAL, INC.		3014144799	2023
	Subsystem, Water Purification - TQE Plus Endotoxin 10" Filter Flat 222 Head; TQE Plus Endotoxin 20" Filter Flat 222 Head; TQE Plus Endotoxin 30" Filter Flat 222 Head		Repackager/Relabeler