

FDA CASE STUDY

→ A fledgling company works to bring its first product to market

REGULATORY PATHWAYS FOR MEDICAL DEVICES: CHOOSING THE RIGHT ONE

THIS FICTIONALIZED CASE STUDY IS THE FIRST IN AN EDUCATIONAL SERIES PUBLISHED BY THE U.S. FOOD AND DRUG ADMINISTRATION.

For 35 years, Henry Neyhard had practiced pediatrics in this 1970s beige brick building. When he first opened his doors, the building seemed hip and modern—a fresh start. Exactly what he needed. After his residency, he had taken a detour in his career and founded a medical device company, combining his love for medicine with his drive for invention. Where others saw problems, he saw solutions. But turning his ideas into reality eluded him. He struggled to get his business off the ground, and funds ran out before his products reached the market. He closed the company and opened his medical practice. Neyhard was a gifted pediatrician, and his patients and practice thrived. And yet, almost daily, a medical instrument or piece of equipment disappointed him. He knew he could do better. At night, on his own time and with his own resources, he tinkered.

All in all, Neyhard had filed more than 20 patents for medical devices over the years. Each time, he was beaten to market by competitors who were more savvy about product development and marketing. He was forced to redevelop the device, sometimes

more than once. It burned off his capital, and the devices never reached the patients he was trying to help.

Neyhard's latest invention: an insulin infusion pump. The device could deliver insulin at preset rates with simple user features, allowing patients to adhere to their regimens with increased compliance. Although the device was intended for adults with diabetes, his ultimate goal was to improve the care of pediatric patients. This time, Neyhard thought, would be different. He would design the device right the first time.

He had reached a crossroads in its development; its key features could be designed to operate electronically or mechanically. Both were appealing. But which design would make it smoothly through the regulatory process to the marketplace? Which one would succeed?

The Protégés

A wiry, energetic young woman with short brown hair stuck her head in his office. Sten Laws. Neyhard had hired her to prepare a business plan and help recruit investors for the development and manufacturing of the insulin infusion device. Laws was finishing business school at the end of the month and had jumped at the chance to get a new venture off the ground. With her was Rush Mooney, a tall, thoughtful engineering student about to graduate from the same university.



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Neyhard had brought him on board to do technology research and support the development of the device. Both Laws and Mooney were part-time employees, at least for now.

Although Neyhard had not made the grad students any promises, he was brilliant, open, and fair. They knew where they stood: if the device succeeded, so would they all. Neyhard would retire from his practice, revive his company, pay down the second mortgage he had taken out to fund his extracurricular inventions, and leave a legacy of improved public health. And Laws and Mooney? They would begin their careers not as entry-level cogs in a wheel, but as executives in an exciting new startup.

First, though, Laws and Mooney would need to understand the regulatory process for medical devices and formulate a strategy. Last time the three met, Neyhard had given them a crash course on the Federal agency that he knew, from experience, could make or break his device: the Food and Drug Administration (FDA). Part of the U.S. Department of Health and Human Services, FDA is responsible for protecting the public health by assuring the **safety, effectiveness,** and security of human and veterinary drugs, vaccines and other biological products, medical devices, the food supply, cosmetics, dietary supplements, and products that give off radiation. FDA also regulates tobacco products.

Neyhard had asked Laws and Mooney to research the FDA and learn all they could about how the agency worked to regulate medical

ABOUT THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Mission:

The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science; providing industry with predictable, consistent, transparent, and efficient regulatory pathways; and assuring consumer confidence in devices marketed in the United States.

Vision:

Patients in the United States have access to high-quality, safe, and effective medical devices of public health importance first in the world. The United States is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety. U.S. postmarket surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance. Devices are legally marketed in the United States and remain safe, effective, and of high quality. Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.

Available at: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm300639.htm>

devices. The two students knew they had to show Neyhard they could get up to speed quickly, and they returned to his office today poised to impress.

The Presentation

Not one for small talk, Laws began as soon as the three were settled around a small table in Neyhard's office. "So to market a medical device in the United States, we have to follow the **Federal Food, Drug, and Cosmetic Act**, or the FD&C Act." She glanced at her notes. "At the FDA, the Center for Devices and Radiological Health, or CDRH, evaluates the evidence for the safety and effectiveness of medical devices. Safety means that the device poses no significant **risk** to users, or that the risks are mitigated, meaning

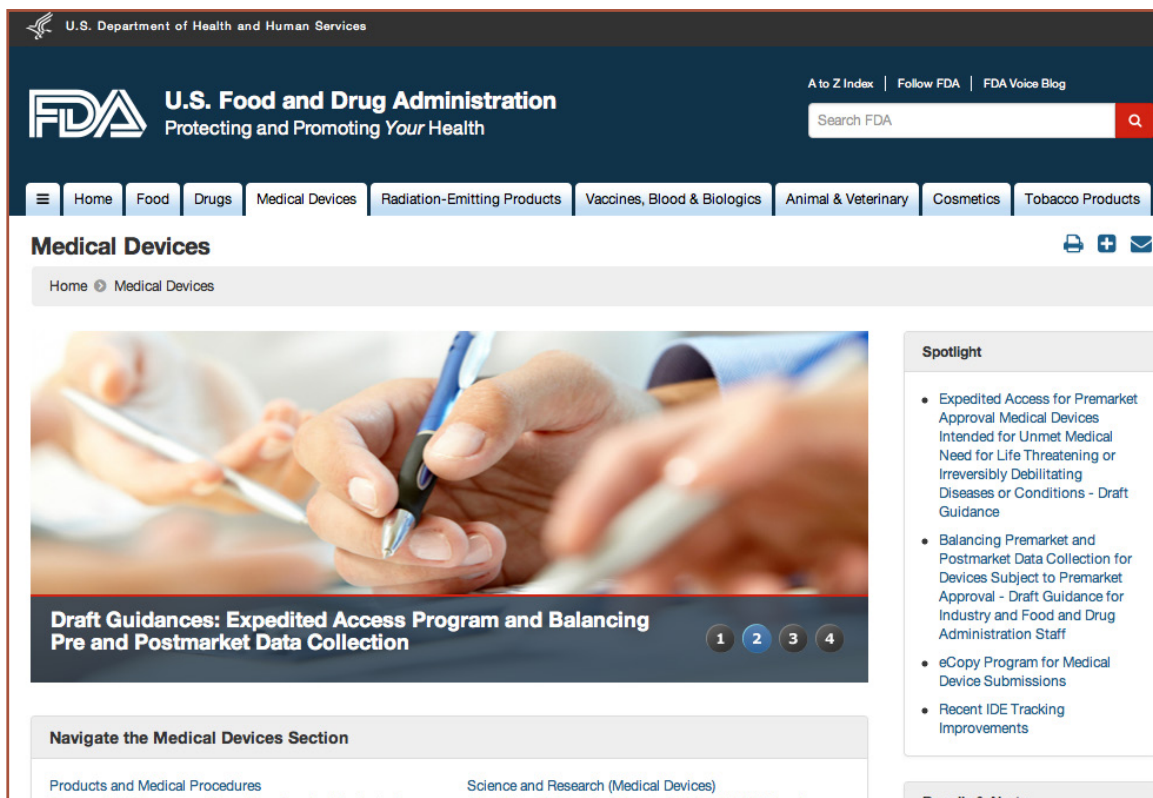
they can be adequately controlled. Effectiveness means the device can treat the disease as labeled." Neyhard nodded. "How did you learn all of this?"

"The FDA's Web site: www.fda.gov. And it's not just dry regulations!" Sensing that she had Neyhard's attention, Laws quickly launched into presentation mode. She popped open her laptop, went to FDA's Web site, and selected the Medical Devices tab, narrating as she went. "There are CDRH Learn video courses, a Device Advice section, and searchable databases." Under Tools and Resources, she clicked on Medical Device Databases and then scrolled down, selecting a database called Product Classification.

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THE FDA WEB SITE



As Mooney and Neyhard watched, Laws typed “infusion pump” in the search box, yielding 13 hits. “This table gives you four types of information: the device name, the three-letter product code, the device class, and the regulation number. It’s updated every week.”

Neyhard frowned. “But what does it mean? What are those four things?”

Laws waved her hand at the screen. “You can read all about them on the Web site, but I’ll give you the abridged version. Device name is the general name, like blood pressure cuff. Device class shows which risk category a type of device falls into and the controls that are necessary to mitigate the risks to

health. A device that’s pretty safe, like a tongue depressor, would be Class I, and a device like a heart-lung bypass machine would be Class III, because problems with one of those could be serious. In between is Class II, for devices that are moderate risk.” Most of the pumps listed in the search results were labeled Class II. “The regulation number shows the part of the **Code of Federal Regulations** that identifies that type of device and establishes the class.

Mooney, who had been listening attentively, now picked up where Laws left off. “Next is the product code. That’s the three-letter abbreviation for that type of device. Knowing the product code makes it a lot easier to search the other

“We want to know the problems with similar infusion pumps already on the market and learn from other people’s experiences. Including their *mistakes*.”

databases. It’s the key to finding more information about devices that are similar to yours.”

Mission accomplished: Neyhard was indeed impressed. In just a few minutes, they had confirmed that FDA regulates infusion pumps as medical devices. They had also learned that Neyhard’s invention, which was not an implantable

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infusion pump, would probably be categorized as a Class II device. Neyhard reached over and started clicking. “We want to know the problems with similar infusion pumps already on the market and learn from other people’s experiences. Including their *mistakes*.”

Laws pointed at Neyhard. “Bingo! From here, we can go to databases on medical device reporting and recalls.”

Neyhard leaned back in his chair. He remembered trying to make sense of the regs over the years... all the money that had gone to legal research, the hours he himself had spent poring over the Federal code. The term Rosetta Stone came to mind. Maybe FDA’s online resources would be a game changer, making the legwork faster. Was time finally on his side?

The Device Design

Neyhard’s expertise is in innovative drug delivery. His latest efforts focus on new ways to administer insulin (the delivery method) and new ways to control how much drug the patient gets over time (the drug release rate). His current challenge is to choose which technology to use in the design of an insulin infusion device. He learned from his previous experience that identifying the right **regulatory pathway** early in the development process could help speed the time to market.

Since their last meeting with Neyhard, Mooney and Laws had compiled information about insulin pumps from the CDRH

Web site, including the regulatory requirements for producing and marketing them, and they researched the problems that had been reported with the pumps already on the market. Drawing on what they found, they drafted a bulleted list of the features they had decided to recommend to Neyhard. Mooney brought the list with him to the coffee shop just off campus, where he was meeting Neyhard.

The two men exchanged greetings, grabbed two coffees, and took a table near the door. Neyhard got right to the point. “Rush, I know your training in engineering can help me tackle this issue. We have the formula on the drug release rate, and we’ve nailed down the critical attributes and parameters. Now how are we going to design the method of delivery—electronically or mechanically? I know you’ve been looking at the regulatory requirements with Sten. Have you learned enough to know which technology has a better chance of standing up to regulatory scrutiny and succeeding in the marketplace?”

As always, Mooney paused for a moment to compose his thoughts. Through the FDA Web site, he had learned that software issues were one of the most common problems with infusion pumps. He pulled his smart phone from his pocket. “I like electronics. I *love* my smart phone. I use it to organize my life, find information whenever I need it, and play games and videos. But unlike a lot of my friends, I still have a landline. Why? My smart phone demands constant program updates and upgrades to fix bugs and improve functionality, and every

“Now how are we going to design the method of delivery—electronically or mechanically?”

once in a while, it freezes. Not my landline. It does just one thing, but it does it well and consistently and cheaply. That’s what your device needs to do to succeed.” He handed his boss the list of proposed design features. “We think your technology would work best in a nonelectronic, fully disposable insulin infusion device.”

Neyhard scanned the list as he sipped his coffee. He understood the young engineer’s point, and he appreciated its simplicity and pragmatism. He was a physician with a small business, not a techie with a fleet of developers at the ready. An electronic device may have some advantages, but small unforeseen flaws could be its downfall, slowing development and threatening its reliability and regulatory passage. A mechanical device had the potential to benefit more patients and improve public health. It would be more economical to manufacture, its prospects for reimbursement more favorable, and the return on investment greater. “Let’s look at mechanical infusion devices that are similar to my device. Those CDRH databases will make it easy to figure out what’s already on the market.”

“I’m on it,” said Mooney, rising to leave. He was glad he had already begun researching infusion devices and their problems, and now he was ready to zero in on mechanical infusion pumps.

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The Path to Market

Neyhard and his team had decided to focus on designing a mechanically operated, single user, fully disposable insulin infusion device. Their decision was based on instinct and confirmed by the free information gathered from the CDRH Web site. They had considered financial, technological, and regulatory issues extensively. Today, the grad students returned to Neyhard's office to move forward with the next phase of their project.

Neyhard closed the door and sat at the head of the table in the small conference room. "Sten and Rush, you've done well. In just a short time, you've used the FDA Web site to find regulatory and product information, uncover pitfalls in other products that we can now avoid, and identify competing products on the market." The two students exchanged pleased glances.

Laws nodded excitedly. "And we've agreed that a simple mechanical design will allow users better control than our competitors' devices offer. That will make it easier for patients to adhere to therapy, which may improve outcomes. And *that* should attract the interest of investors, providers, and payors."

Neyhard smiled at her enthusiasm. "Now how do we go about preparing our submission to CDRH?"

"It all depends on our business strategy, Dr. Neyhard," Laws answered.

"That's exactly right," Neyhard said. He held up a thick portfolio. "Exhibit

"For this new device, we'll need to write a convincing business and regulatory plan that will attract investors."

A: My business plan from my last project. It had a lot of technical information about my invention, but it didn't cover how we were going to manufacture it safely and reliably, or how we were going to get regulatory approval to market it. For this new device, we'll need to write a convincing business and regulatory plan that will attract investors. My top concern is having a public health impact, but potential backers will be most focused on their return on investment."

Laws agreed. "Before we can sell your device in the United States, we have to obtain either **approval** or **clearance** from CDRH. If we can prove your device is novel or if it is high risk, you can seek **premarket approval**, or PMA. That would allow the product to be legally marketed in the United States."

Neyhard looked impatient. "So let's get started on PMA."

Laws shook her head. "PMA is for high-risk devices, Class III. It usually requires clinical trials to gather data that demonstrate safety and effectiveness, which involves additional time and investment. And to use a device in a trial, you may have to submit another application, for an **Investigational Device Exemption**, or IDE. The IDE allows a device to be used only in trials, not commercially. If the device is eventually approved, the market adoption could be greater if the device addresses an unmet public

health need. The whole process could take years, and you need to have a realistic business plan."

Neyhard drummed his fingers on the table. "You're right, it would be long and costly. That could spook investors."

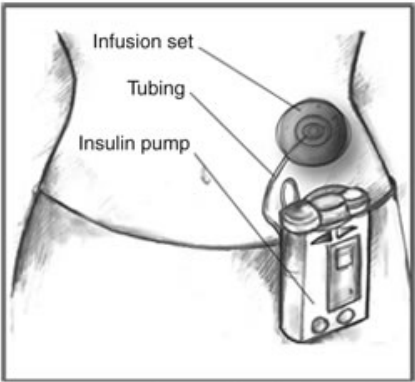
Mooney spoke next, displaying his usual quiet confidence. "Remember, we think your pump is a Class II device, which puts us on a different path. Now, we've already sized up our competition, which is just good business. But in our case, it's critical for another reason: we may be able to cite a competing product as a **predicate device**. So, let's start by finding a similar legally marketed device that we can use as the predicate and document that the **intended uses** of the products are the same. Then, we'll demonstrate that even if there are technological differences between the two devices, these differences don't raise different questions of safety and effectiveness. We'll also need to provide sufficient performance data to demonstrate that your device is at least as safe and effective as the predicate. This pathway is called **premarket notification**, or 510(k)."

Laws continued, "And if all goes well, we're golden. But if we *can't* find a predicate device, or if we submit a 510(k) application but FDA finds that your device is *not* **substantially equivalent**, there's still another path: the de novo process. We'll cross that bridge if we come to it."

"Back up," said Neyhard. "Rush, you mentioned data. How do we get that?"

REGULATORY PATHWAYS FOR MEDICAL DEVICES:
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INSULIN
INFUSION PUMP



Mooney was ready. “Class II devices are subject to regulations that the FDA calls **general controls** and **special controls**. That means we’ll have to follow the Quality System Regulation, also known as **Current Good Manufacturing Practices**, cGMPs, or **GMPs**. It’s all about quality assurance—making sure the product’s design, packaging, labeling, and manufacturing meet certain standards, and the data provided for evaluation are sound.

We’ll need to apply statistics to product development activities, things like verification testing and process validation.”

Neyhard leaned forward. “What else do we need to put in our business plan? We need to show that we are looking forward.”

Laws pulled out a timeline showing next steps. “There are a lot of things to do, but many of them can be done at the same time. We’ll identify the relevant regulations, standards, and guidance documents. While we are preparing for the submission process and planning the studies, we could seek advice from FDA through the Pre-Submission process and potentially be successful. Once we get clearance for marketing, we’ll need to register and list the device

Mooney and Laws shifted nervously in their seats. What had they missed?

with the FDA. And we’ll need to be sure that postmarket surveillance controls are in place, like Medical Device Reporting, which includes tracking of adverse events. Then, we go to market with your device!”

Neyhard held up one hand. “Stop right there.”

Mooney and Laws shifted nervously in their seats. What had they missed?

Neyhard laughed. “I mean stop calling it my device! It’s *our* device. You two have really demonstrated your commitment to this product and to our new company. You helped refine the design, and I’m convinced that we’ll get the financing and regulatory approval we need. Now finish your exams and get ready to report for work. I leased new office space downtown this morning.”

➔ COMPARISON OF 510(k) AND PMA SUBMISSIONS

510(k)	PMA
Primarily for Class II devices (moderate risk)	Primarily for Class III devices (high risk)
A legally marketed "predicate" device exists	A Class I or II legally marketed predicate device does not exist
Documented proof of substantial equivalence to predicate device is required	Device is life supporting or life-sustaining, of substantial importance in preventing impairment of human health, or can present a potential unreasonable risk of illness or injury
	Documented reasonable safety and effectiveness data for the device are required

Note: See glossary for additional information.

REGULATORY PATHWAYS FOR MEDICAL DEVICES: CHOOSING THE RIGHT ONE CONTINUED

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CLASSIFYING YOUR MEDICAL DEVICE

- 1** First, determine whether the product is a medical device according to the definition of the law, section 201(h) of the FD&C Act, falling under the authority of CDRH. Biological products are handled by the Center for Biologics Evaluation and Research; drug products are handled by the Center for Drug Evaluation and Research.



- 2** Second, identify and classify the device to determine its risk level. The three device classes are based on risk and have different regulatory controls to assure reasonable safety and effectiveness. (See <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm>)

- Class I devices present a low risk of harm to the user and are subject to general controls that are sufficient to protect the user. Most are typically exempt from submitting a 510(k), but still need to comply with other regulations, such as QSR, registration and listing (R&L), etc.
- Class II devices are those for which general controls alone are not sufficient to assure safety and effectiveness, and existing methods are available to provide such assurance. They are also subject to special controls.
- Class III devices present a high risk of harm to the user and are usually used to sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. Most of these devices require PMA, because general and special controls alone cannot reasonably assure their safety and effectiveness.



- 3** Third, identify one of three common ways to apply for marketing authorization of your medical device by CDRH:

1. **Premarket Notification—510(k):** A medical device that is similar to another medical device already being legally marketed must be cleared through a regulatory process called premarket notification. Section 510(k) of the FD&C Act

prescribed premarket notification; therefore, the process is commonly called the 510(k) process. FDA may issue an order of substantial equivalence only upon making a determination that the device to be introduced into commercial distribution is as safe and effective as a legally marketed device. This legally marketed device is called the predicate device for the device that is seeking clearance.

2. **Premarket Approval—PMA:** PMA is an application for the approval to allow high-risk devices to be put into commercial distribution. PMA allows a device maker to demonstrate to FDA that the device is reasonably safe and effective on its own. Before a novel medical device can be legally put into commercial distribution, by law it is required to demonstrate its safety and effectiveness.

3. **De Novo Classification:** There are two pathways to initiate the de novo process:

- **A request for de novo classification:** A 510(k) submission that leads to a determination of “not substantially equivalent” may be followed by a petition for de novo classification. This is a process that provides a route to market for medical devices that are low to moderate risk but have been classified in Class III, because FDA has found them to be not substantially equivalent to legally marketed predicate devices.

- **A direct de novo request to FDA to make a risk based classification of the device into Class I or Class II** can be initiated when there is no legally marketed device upon which to base a determination of substantial equivalence without first submitting a 510(k) and receiving a not substantially equivalent (NSE) determination.

Investigational Device Exemption—IDE: IDE refers to a regulatory submission to study the device in human subjects. Its purpose is to allow devices that are in a developmental stage to be used in a clinical study in order to collect safety and effectiveness data required for a PMA application or a 510(k) submission. It allows “exemption” of the manufacturer to lawfully ship and study the investigational device in the targeted population.

REGULATORY PATHWAYS FOR MEDICAL DEVICES:
CHOOSING THE RIGHT ONE CONTINUED



ACRONYMS

➤ 510(k)	Premarket Notification
➤ CDRH	Center for Devices and Radiological Health
➤ CFR	Code of Federal Regulations
➤ cGMPs	Current Good Manufacturing Practices
➤ FD&C Act	Federal Food, Drug, and Cosmetic Act
➤ FDA	Food and Drug Administration
➤ GMP	Good Manufacturing Practices
➤ IDE	Investigational Device Exemption
➤ PMA	Premarket Approval
➤ QSR	Quality System Regulations



GLOSSARY

Approval: Approval of a medical device must be obtained from the FDA by demonstrating that the device is reasonably safe and effective, and that the benefits outweigh the risks for the intended patient population before it can be put into commerce.

Clearance: Clearance of a medical device not exempt from 510(k) must be obtained from the FDA by demonstrating substantial equivalence to its predicate device(s) before it is put into commerce.

Code of Federal Regulations: The Code of Federal Regulations (CFR) is the codification of the general and permanent rules and regulations (sometimes called administrative law) published in the Federal Register by the executive departments and agencies of the U.S. Federal Government.

Current Good Manufacturing Practices (cGMP): These are production and testing practices that help ensure safe, effective, and quality products. In the United States, cGMP Regulations are promulgated by the

FDA under the authority of the FD&C Act (Chapter IV for food; Chapter V, Subchapters A, B, C, D, and E, for drugs and devices). The “c” stands for “current”, reminding manufacturers that they must employ up-to-date technologies and systems to comply with the regulation. It is the manufacturers’ responsibility to be current.

Effectiveness: There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use will provide clinically significant results. (21 CFR Part 860.7)

Federal Food, Drug, and Cosmetic Act (FD&C Act): This is a set of laws passed by Congress in 1938 giving authority to the FDA to oversee the safety of food, drugs, and cosmetics. The Act has been amended many times, most recently to add requirements about bioterrorism preparations and user fees.

REGULATORY PATHWAYS FOR MEDICAL DEVICES: CHOOSING THE RIGHT ONE CONTINUED

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General Controls: General controls include the following:

- Establishment Registration of companies required to register under 21 CFR Part 807.20, such as manufacturers, distributors, repackagers, and relabelers
- Medical Device Listing with FDA of devices to be marketed
- Manufacturing devices in accordance with GMP in 21 CFR Part 820 (Quality System Regulation)
- Labeling devices in accordance with labeling regulations in 21 CFR Part 801 or 809
- Submission of a premarket notification or 510(k) before marketing a device

Good Manufacturing Practices (GMP): These are production and testing practices that help ensure safe, quality products. In the United States, GMP Regulations are promulgated by the FDA under the authority of the FD&C Act (Chapter IV for food; Chapter V, Subchapters A, B, C, D, and E, for drugs and devices). GMP is also sometimes referred to as cGMP.

Intended Use/Indication for Use: “Intended use” means the general purpose of a device, or what the device does, and encompasses the indications for use. “Indications for use” describes the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.

Investigational Device Exemption (IDE): IDE refers to the regulations under 21 CFR Part 812. A regulatory submission to study a medical device in human subjects. IDEs are only required for studies performed in the United States. An IDE allows an investigational device to be used in a clinical study to collect the safety and effectiveness data required for a marketing application. An approved IDE means that the IRB (and FDA for significant risk devices) has approved a sponsor’s study application.

Predicate Device: A legally marketed device to which a new device may be compared for a determination

regarding substantial equivalence because the devices have the same intended use and the same technological characteristics, or different technological characteristics that do not raise different questions of safety and effectiveness.

Premarket Approval (PMA): The FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Any Premarket Approval application for a Class III medical device, including all information submitted with or incorporated by reference therein (21 CFR Part 814.3). Class III devices are those that cannot be classified as Class I or Class II devices because insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and either (1) are purported to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health; or (2) present a potential unreasonable risk of illness or injury.

Premarket Notification—510(k) Clearance: Section 510(k) of the FD&C Act requires device manufacturers, who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as premarket notification—also called PMN or 510(k). This allows FDA to determine whether the device in question is equivalent to a device already placed into Class I, Class II, or Class III requiring 510(k), or a legally marketed preamendment device. Thus, “new” devices (not in commercial distribution prior to May 28, 1976) that have not been classified can be properly identified. Specifically, medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use.

REGULATORY PATHWAYS FOR MEDICAL DEVICES: CHOOSING THE RIGHT ONE CONTINUED

Regulatory Pathways: Before a medical device can be marketed, the manufacturer must submit evidence that demonstrates product safety and effectiveness to the Office of Device Evaluation of CDRH and to the Office of In Vitro Diagnostics and Radiological Health at FDA. There are various submission processes and applications for evaluation. Regulatory pathways include PMA, PMA Supplement, Product Development Protocol, Humanitarian Device Exemption, IDE, IDE Amendment, IDE and 510(k), Supplement, and De novo.

Risk: The combination of the probability of occurrence of harm and the severity of that harm.

Safety: There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to

health from use of the device for its intended uses and conditions of use outweigh any probable risks. (21CFR Part 860.7)

Special Controls: Special controls may include the following:

- Special labeling requirements
- Mandatory performance standards
- Postmarket surveillance

Substantial Equivalence: As part of the 510(k) process, FDA may issue an order of substantial equivalence if it determines that a new medical device is as safe and effective as a similar device already being legally marketed, called the predicate device.

STUDENT ACTIVITIES

SESSION 1: BEFORE CLASS

I. Review the following CDRH Learn videos:

1. Overview of Regulatory Requirements: Medical Devices

(approximately 30 minutes)

<http://fda.yorkcast.com/webcast/Viewer/?peid=040308365ec8405bad39b06de8561bdc1d>

2. The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications or 510(k)s

(approximately 1 hour)

- a. <http://fda.yorkcast.com/webcast/Viewer/?peid=f59814465f674e59a19f3b61c6880ea81d>
- b. <http://fda.yorkcast.com/webcast/Viewer/?peid=e0ea02ad4f0c4532a98fa9406caa01d0>
- c. <http://fda.yorkcast.com/webcast/Viewer/?peid=2360fdf6adf7468aaebd0431ffd76ace>

3. The Investigational Device Exemption (IDE) Process

(approximately 30 minutes)

- a. <http://fda.yorkcast.com/webcast/Viewer/?peid=8553ad7df9054febb5ef0048e359ad1e1d>
- b. <http://fda.yorkcast.com/webcast/Viewer/?peid=46344ca5abbb465e88404a92eed542f71d>

II. Answer the following questions:

1. What is the definition of a medical device according to the Federal Food, Drug, and Cosmetic (FD&C) Act?
2. Give three examples of medical devices you have seen in a pharmacy or hospital.
3. Name and describe the ways in which a medical device company may obtain “clearance” of its product before putting it into commerce.

REGULATORY PATHWAYS FOR MEDICAL DEVICES: CHOOSING THE RIGHT ONE CONTINUED

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4. Name and describe the ways in which a medical device company may obtain “approval” of its product before putting it into commerce.

III. References

Note: Draft guidances are subject to change and are not for implementation.

1. The FD&C Act
<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm>
2. Subchapter II—Definitions (§ 321; pg 32, paragraph h)
<http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapII-sec321.pdf>
3. FDA Decisions for IDE Clinical Investigations
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279107.pdf>
4. Premarket Approval (PMA)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm>

SESSION 1: IN CLASS

I. Access medical device databases

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>

1. Product classification database
2. 510(k) database
3. PMA database
4. Adverse events database

II. Questions for in-class discussion

1. What are the three major problems of infusion pumps?
2. Name all the product codes of infusion pumps.
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm>
3. Identify the potential product code of Neyhard’s device and its likely regulation.
4. What is the potential product classification of Neyhard’s invention?
5. What are the likely top three issues for Neyhard’s predicate device(s)?

III. References

Note: Draft guidances are subject to change and are not for implementation.

1. Infusing Patients Safely: Priority Issues From the AAMI/FDA Infusion Device Summit
http://www.aami.org/htsi/infusion/summit/AAMI_FDA_Summit_Report.pdf
2. Infusion Pump Improvement Initiative
<http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/UCM206189.pdf>

SESSION 2

I. Complete the following before class:

1. Review the IDE, PMA, and 510(k) processes.
2. Determine the intended use of Neyhard’s infusion device.
3. Identify special controls and general controls, and give examples.

REGULATORY PATHWAYS FOR MEDICAL DEVICES: CHOOSING THE RIGHT ONE CONTINUED

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II. Questions for in-class discussion

1. Propose the best pathway for Neyhard to present to his potential investors.
2. Justify your proposed pathway.
3. How would you determine whether there is a need for clinical evaluations?
4. Justify your decision to do or not do clinical evaluations(s).
5. Share the lessons you have learned from the case.

III. References

Note: Draft guidances are subject to change and are not for implementation.

1. The New 510(k) Paradigm
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf>
2. Total Product Life Cycle: Infusion Pump—Premarket Notification [510(k)] Submissions
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM209337.pdf>
3. 510(k) “Substantial Equivalence” Decision Making Process
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134783.htm>

4. FDA Decisions for IDE Clinical Investigations
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279107.pdf>
5. IDE for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human Studies
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279103.pdf>
6. PMA
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.html>
7. Medical Device Classification Product Codes
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM285325.pdf>
8. Requests for Feedback on Medical Device Submissions: The Pre-Submission Program
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf>