



# Regulatory Overview and Pathways



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# What is a Device?

- **Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act:**

“The term ‘device’ ... means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory which is:

1. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. Intended to affect the structure or any function of the body of man or other animals, and

Which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. The term ‘device’ does not include software functions excluded pursuant to section 520(o).”



# CDRH 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 U.S.

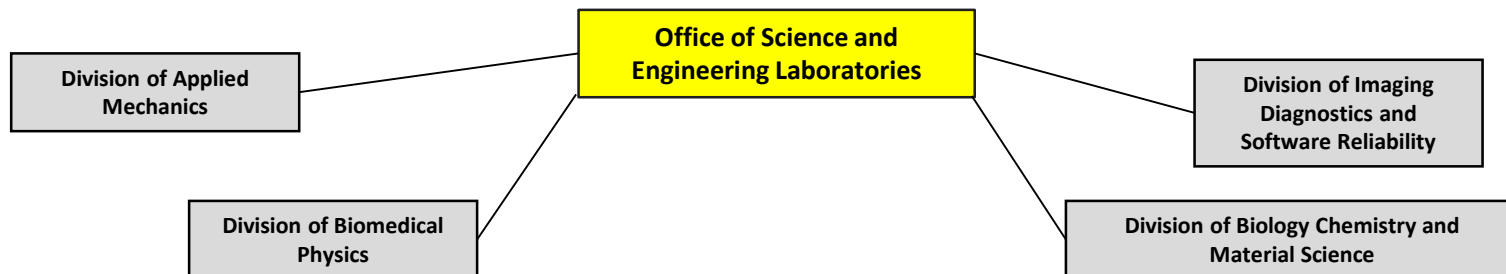
# Office of Science and Engineering Laboratories (OSEL)



## OSEL Mission:

- Ensure readiness for emerging and innovative medical technologies
- Develop appropriate evaluation strategies and testing standards
- Create accessible and understandable public health information
- Deliver timely and accurate decisions for products across their life cycle

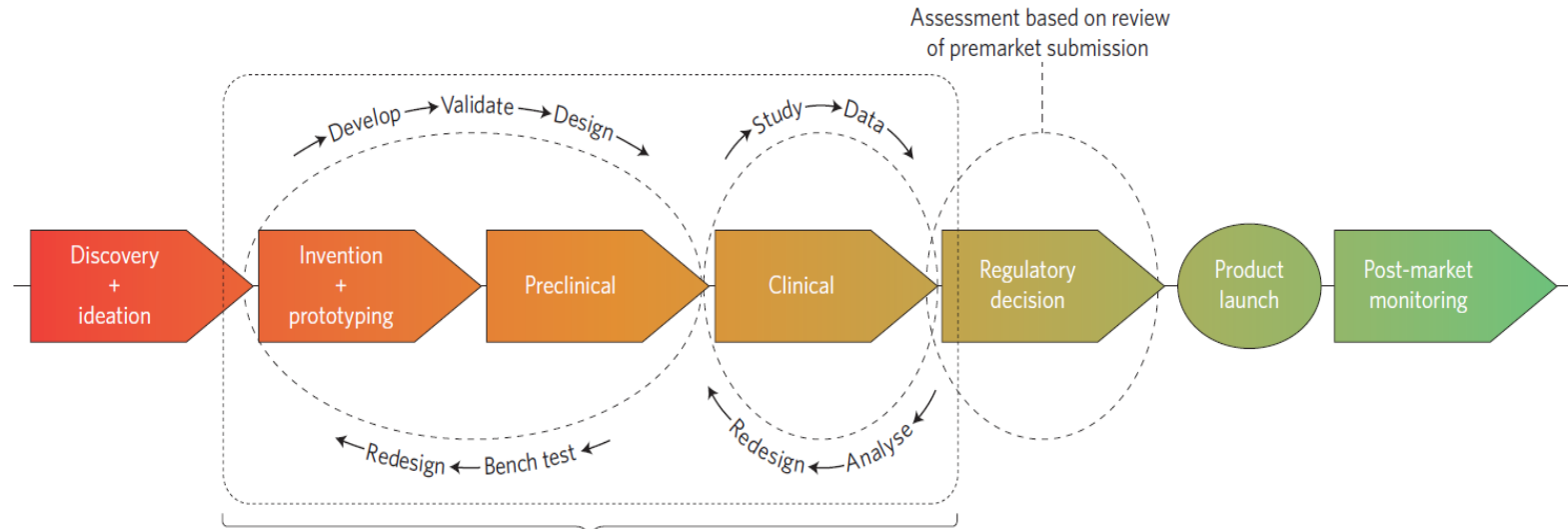
Through a culture of Customer first, Communication, Collaboration and Consultancy



# Facilitating Medical Device Innovation



- Partnerships are becoming increasingly important to everyone
  - >80% of device companies have <50 staff
  - CDRH/OSEL wants to build a scientific bridge with the small, innovative companies
  - Decoupled from any formal regulatory process
  - Intended to lend assistance in development of new evaluation strategies and methods



# Office of Device Evaluation (ODE)

- ODE is responsible for the program areas through which medical devices are evaluated, cleared, or approved for clinical trials and marketing.
- The major programs administered by ODE are:
  - Premarket notification (510(k))
  - De Novo Classification
  - Premarket Approval Applications (PMAs)
  - Humanitarian Device Exemptions (HDEs)
  - Investigational Device Exemptions (IDEs)
  - Pre-submissions (Q-Subs)





# Classification of Devices



- Section 513(a)(2) of FD&C Act requires FDA to **determine safety and effectiveness** of a device by weighing any **probable benefit** against any **probable risk of injury or illness** from such use
- Risk based classification
  - **Class I (general controls)** – Low risk
  - **Class II (special controls)** – Moderate risk
  - **Class III (premarket approval)** – High risk



# Class I Devices

- Low risk devices
- Class I devices typically do not require FDA premarket review prior to being marketed
- General controls are sufficient to provide a reasonable assurance of safety and effectiveness, e.g.:
  - Adulteration
  - Misbranding
  - Banned/Restricted Devices
  - Registration and Listing Requirements
  - Quality System Regulation and Good Manufacturing Practices (GMP) (some exempt)
- Examples?



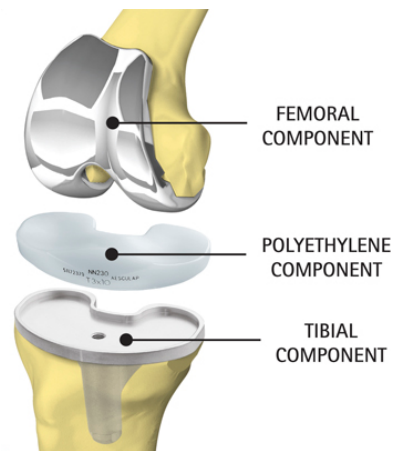
<http://www.sklarcorp.com/instrument-sets/orthopedic-surgery/basic-orthopedic-surgery-set.html>



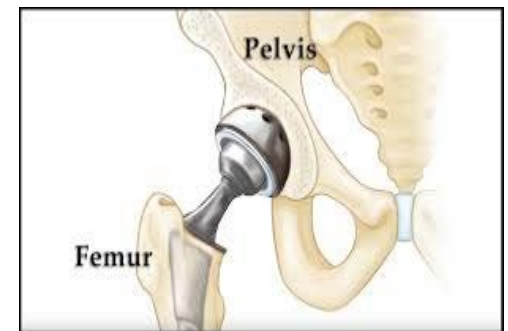


# Class II Devices

- **Moderate risk devices**
- General controls alone are not sufficient for a reasonable assurance of safety and effectiveness and for which there is sufficient information to establish special controls to provide such assurance
- **Premarket notification typically required – 510(k)**
- Typical special controls
  - Performance testing (e.g., Animal, Bench)
  - Biocompatibility
  - Packaging
  - Stability/Shelf Life
  - Sterilization/Reprocessing
- Examples?



<https://www.soactivesofast.com/knee/types-of-knee-implants>



<https://orthoinfo.aaos.org/en/treatment/total-hip-replacement/> 9



# Class III Devices

- **High risk devices**
- Insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness
- **Premarket approval (PMA) required to be legally marketed**
- Determination of reasonable assurance of safety and effectiveness based on upon valid scientific evidence
- Premarket evaluation of QSR typically conducted, including preapproval inspection
- Examples?



<http://www.medtronic.com/us-en/patients/treatments-therapies/cervical/treatment-options/cervical-disc-replacement.html>



<http://www.medicalexpo.com/prod/zimmer/product-74894-525679.html>



# 513(g)

- Section **513(g) of FD&C Act** provides a means for obtaining FDA's views about classification and regulatory requirements of a device.
- Submission contains:
  - Device overview (pertinent technology)
  - Proposed intended use and indications for use
  - Proposed classification/regulation
- <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM209851.pdf>

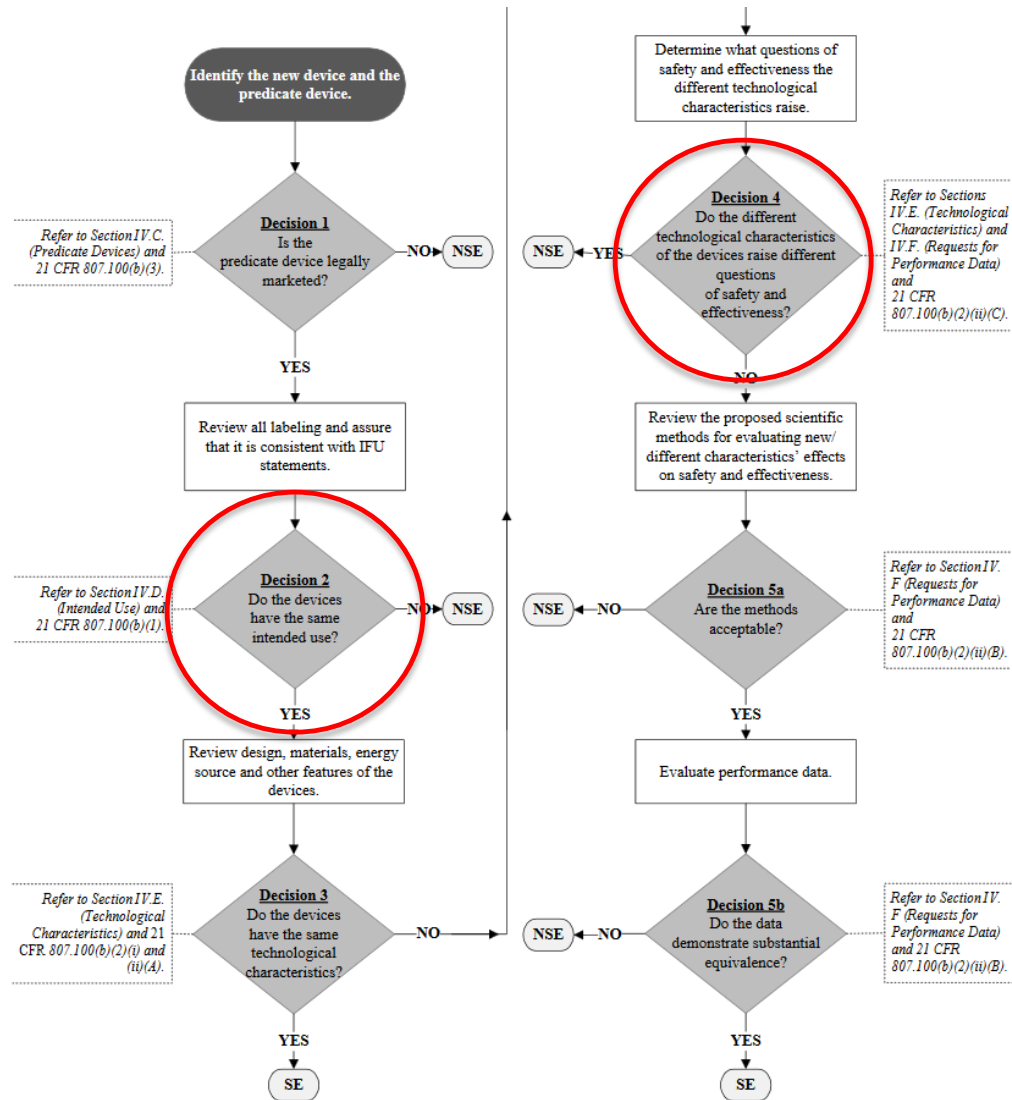
# Premarket Notification (510(k))



- Evaluation of “**Substantial Equivalence**” to previously cleared or Pre-Amendment device (**Predicate**)
- This submission is known as a Premarket Notification (PMN) or 510(k)
- <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm>



# 510(k) Decision Making



SE = "Substantially Equivalent"  
 NSE = "Not Substantially Equivalent"  
 IFU = "Indications For Use"

This Flowchart is not intended to be used as a 'stand-alone' document and should only be considered in conjunction with the accompanying text in this guidance.



# De Novo Classification

**What about products without a predicate and may be low to moderate risk?**

- This is a **classification process**
  - Identify probable risks to health and determine whether general and/or special controls mitigate those risks
  - Can general and/or special controls provide a reasonable assurance of safety and effectiveness?
  - Determine probable benefit versus probable risks
- <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm273903.pdf>



# Premarket Approval (PMA)



- Section **515 of FD&C Act**
- Review of data to establish reasonable assurance of safety and effectiveness
- Typically (almost always) has **clinical data** to demonstrate reasonable assurance of safety and effectiveness
- GMP (manufacturing) review and inspection
- A Summary of Safety and Effectiveness Data (SSED) is prepared and made publicly available
- <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm050289.htm>

# Investigational Device Exemption (IDE)

- **IDE Device Advice**

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm>

- Requirements based on risk
  - Non-significant risk (IRB approval)
  - Significant risk (FDA and IRB approval)







# Pre-Submissions

- Q-submissions are a mechanism for **requesting FDA's feedback prior to a premarket device submission**. It is valuable resource for both medical device applicants and FDA.
- **Pre-Submissions (Pre-Sub)**
  - Requests FDA's feedback on items necessary to guide product development and/or a future IDE or marketing application
  - Includes specific questions regarding review issues relevant to a planned IDE or marketing application



# Purpose of Pre-Submission

- Introduction to a novel device or technology
- Design of a clinical protocol
- Discussion of specific pre-clinical data or testing approach
- Discussion of upcoming submission





# Specific Pre-Sub Questions for FDA

“Good” Pre-Sub Questions	“Bad” Pre-Sub Questions
Does my device require clinical validation?	If I win this trial, will my device be approved?
Will this alternative to clinical data be acceptable?	Do the results from these test reports look good to FDA?
Is this specific area of the bench testing plan adequate? (testing plan, not data)	What do I need to do to get approval?
Is this specific animal testing plan adequate?	
Is this specific clinical approach appropriate?	

For more information refer to “Requests for Feedback on Medical Device Submissions: The PreSubmission Program and Meetings with Food and Drug Administration Staff”

(<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf>)



# Office of Compliance (OC)



The Office of Compliance's (OC) mission is to protect and promote public health by evaluating, enhancing, and ensuring compliance with medical device laws, resulting in the availability of high-quality medical devices.



## What do we do?

- Review of certain device manufacturing site inspections
- Premarket Approval (PMA) Manufacturing and Site-Change Supplements
- Review of post-market corrections/removals (Recalls)
- Review of allegations of regulatory misconduct



# Post-Market Points for your Firm to Consider

- Does your firm's quality system (GMP) ensure high quality, safe and effective medical devices?
- Do changes made to your firm's device, including labeling, require a new pre-market submission?
- Is your device labeling truthful and non-misleading?
- Are your firm's post-market actions, (e.g. Medical Device Reports, Recalls) being reported to the FDA as appropriate?

If you have questions about a post-market issue, please contact FDA. We are here to help!



# Education Resources

## 1. CDRH Learn – Multi-Media Industry Education

- over 80 modules
- videos, audio recordings, power point presentations, software-based “how to” modules
- mobile-friendly: access CDRH Learn on your portable devices

<http://www.fda.gov/Training/CDRHLearn>

## 2. Device Advice – Text-Based Education

- comprehensive regulatory information on premarket and postmarket topics

[www.fda.gov/MedicalDevices/DeviceRegulationandGuidance](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance)

## 3. Division of Industry and Consumer Education (DICE)

- Contact DICE if you have a question
- Email: [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)
- Phone: 1(800) 638-2014 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)

▪Web: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm>

## 4. Division of Orthopedic Devices

- Phone: (301)-796-5650



Thank You!