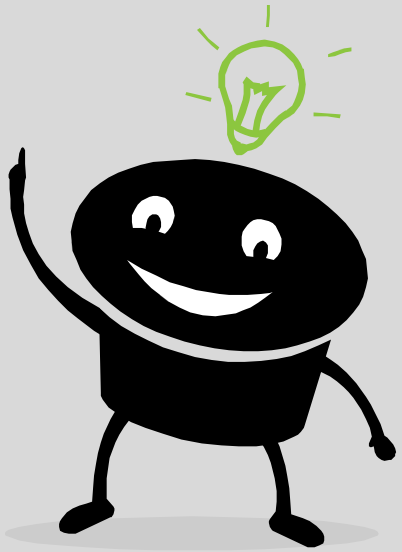
510(k) Program: Case Study

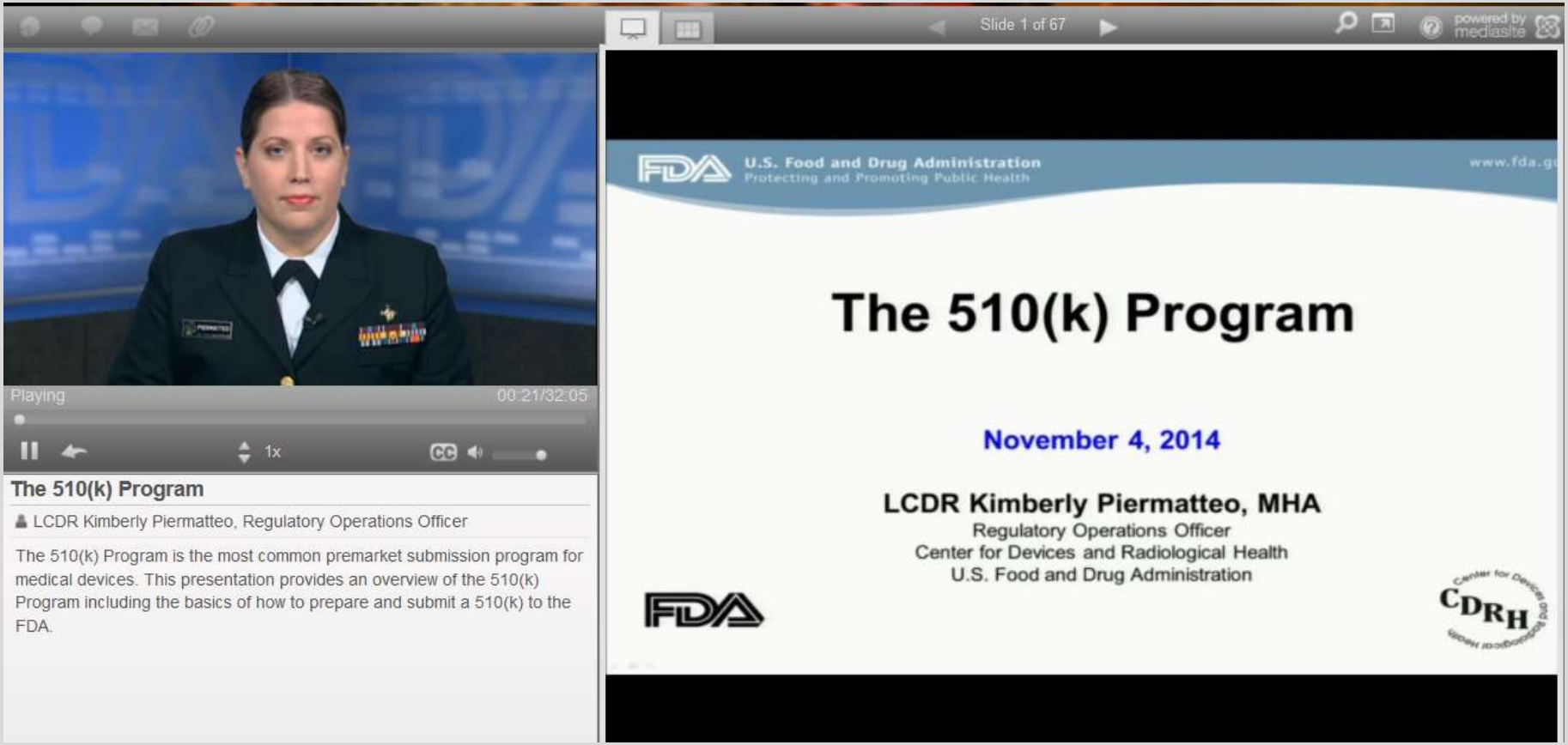
FDA Small Business
Regulatory Education for Industry (REdI)
Burlingame, CA
May 15, 2018

CDR Kimberly Piermatteo, MHA
Consumer Safety Officer
Premarket Programs Branch
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

A Premarket Notification [510(k)] is the most prolific way to bring a new device to market.



Useful Resource: CDRH Learn Module



Learning Objective

The Five 510(k) How To's

1. **How to** determine the appropriate regulatory pathway
2. **How to** identify an appropriate predicate device
3. **How to** prepare a 510(k) submission
4. **How to** demonstrate substantial equivalence
5. **How to** legally market a 510(k) cleared device

Room air consists of approximately:

+ 78% nitrogen

+ 1% other gases

+ **21% ???**

= 100%

Poll Question

Room air consists of approximately 21% of:

A. Argon

B. Carbon Dioxide

C. Oxygen

Room air consists of approximately:

+ 78% nitrogen

+ 1% other gasses

+ **21% oxygen**

= 100%

Pulse Oximeter

- Commonly used to evaluate a patient's oxygen status
- Measures peripheral oxygen saturation (SpO2)
- Non-invasive
- Used in a variety of clinical settings
- Global pulse oximeter market = ~USD 2,393.3 million by 2022*

* Zion Market Research

Our Proposed Device

- Fingertip pulse oximeter for the non-invasive spot-check of blood oxygen saturation (SpO2) and pulse rate.

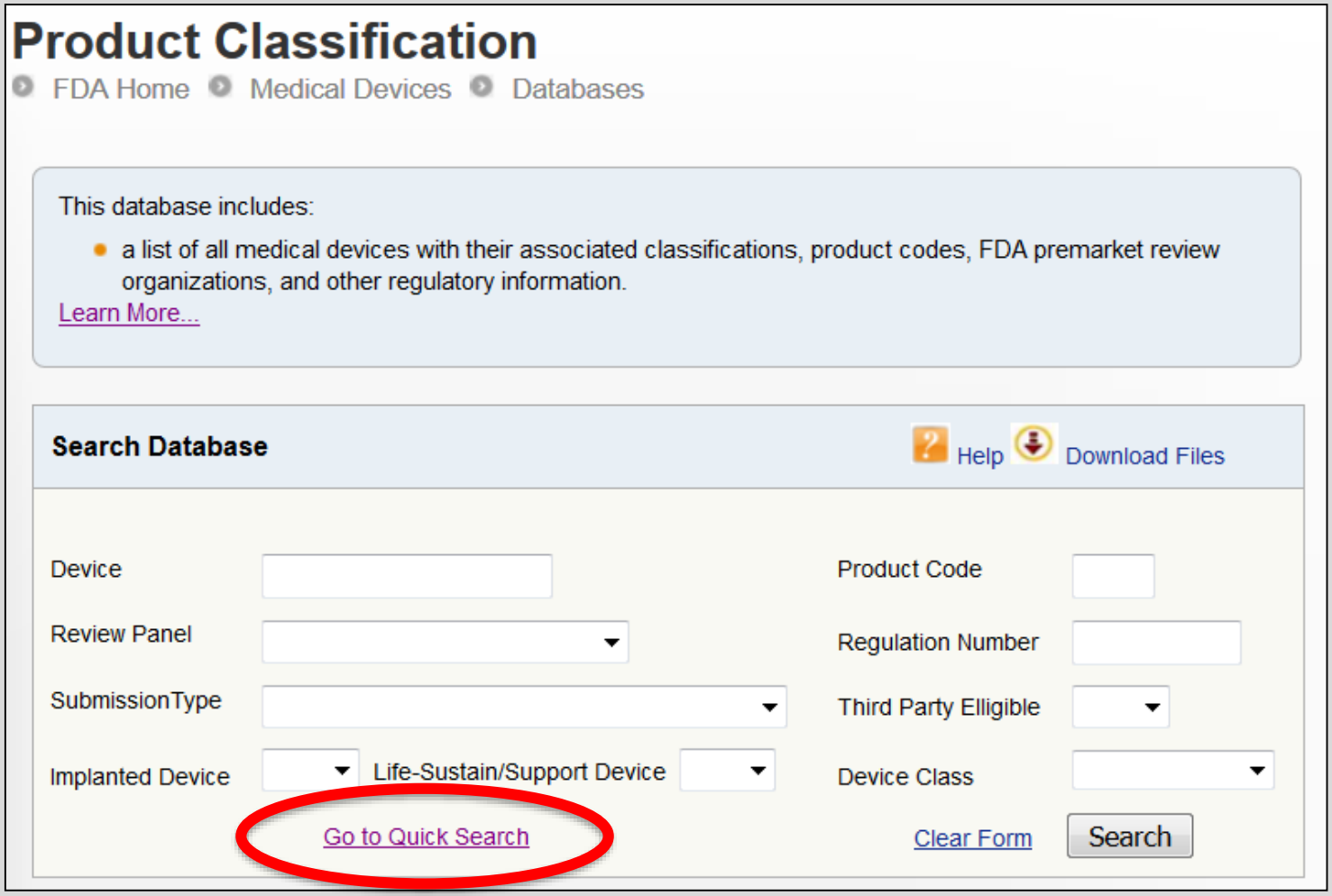
The Five 510(k) How To's

1. **How to** determine the appropriate regulatory pathway
2. How to identify an appropriate predicate device
3. How to prepare a 510(k) submission
4. How to demonstrate substantial equivalence
5. How to legally market a 510(k) cleared device

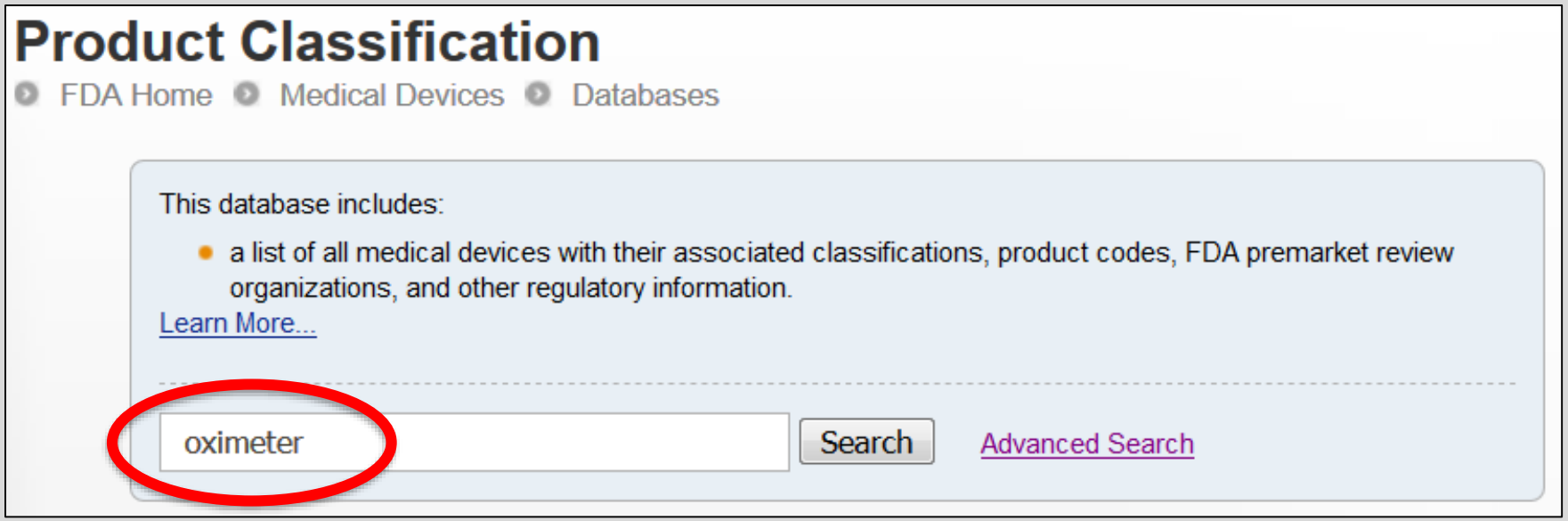
How To #1: Determining the Regulatory Pathway

- Does my product meet the definition of a medical device?
  - If yes, how is it regulated by the FDA?
    - What is the appropriate class?
    - What is the applicable product code?
    - Does this device type require a premarket submission?

Searching the Product Classification Database



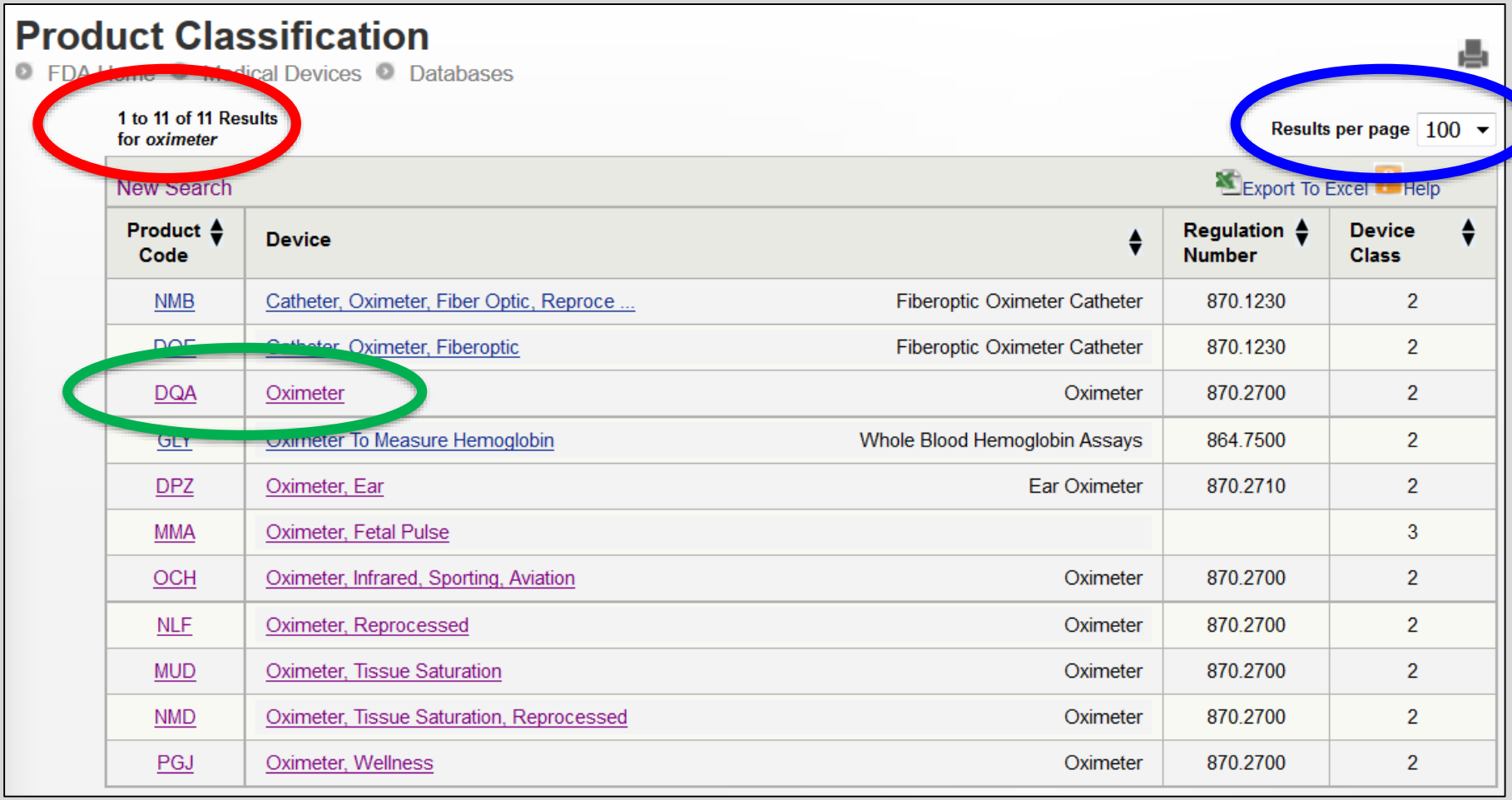
Searching the Product Classification Database



Search Reminders:

- Conduct multiple searches using a variety of related terms
- Spelling matters and avoid plurals
- Don’t be too specific

Searching the Product Classification Database



Product Classification

FDA Home ▸ Medical Devices ▸ Databases

1 to 11 of 11 Results
for *oximeter*

Results per page 100

New Search

Export To Excel | Help

Product Code	Device		Regulation Number	Device Class
NMB	Catheter, Oximeter, Fiber Optic, Reproce ...	Fiberoptic Oximeter Catheter	870.1230	2
DQE	Catheter, Oximeter, Fiberoptic	Fiberoptic Oximeter Catheter	870.1230	2
DQA	Oximeter	Oximeter	870.2700	2
GLY	Oximeter To Measure Hemoglobin	Whole Blood Hemoglobin Assays	864.7500	2
DPZ	Oximeter, Ear	Ear Oximeter	870.2710	2
MMA	Oximeter, Fetal Pulse			3
OCH	Oximeter, Infrared, Sporting, Aviation	Oximeter	870.2700	2
NLF	Oximeter, Reprocessed	Oximeter	870.2700	2
MUD	Oximeter, Tissue Saturation	Oximeter	870.2700	2
NMD	Oximeter, Tissue Saturation, Reprocessed	Oximeter	870.2700	2
PGJ	Oximeter, Wellness	Oximeter	870.2700	2

Product Classification for Oximeter

Device	Oximeter
Regulation Description	Oximeter.
Regulation Medical Specialty	Cardiovascular
Review Panel	Anesthesiology
Product Code	DQA
Premarket Review	Office of Device Evaluation (ODE) Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID) Anesthesiology Devices Branch (ANDB)
Submission Type	510(k)
Regulation Number	[illegible]
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Recognized Consensus Standards

- 1-85 ISO 80601-2-61 First edition 2011-04-01
  Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- 13-54 IEEE ISO 11073-10404 First edition 2010-05-01
  Health informatics - Personal health device communication - Part 10404: Device specialization - Pulse oximeter

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

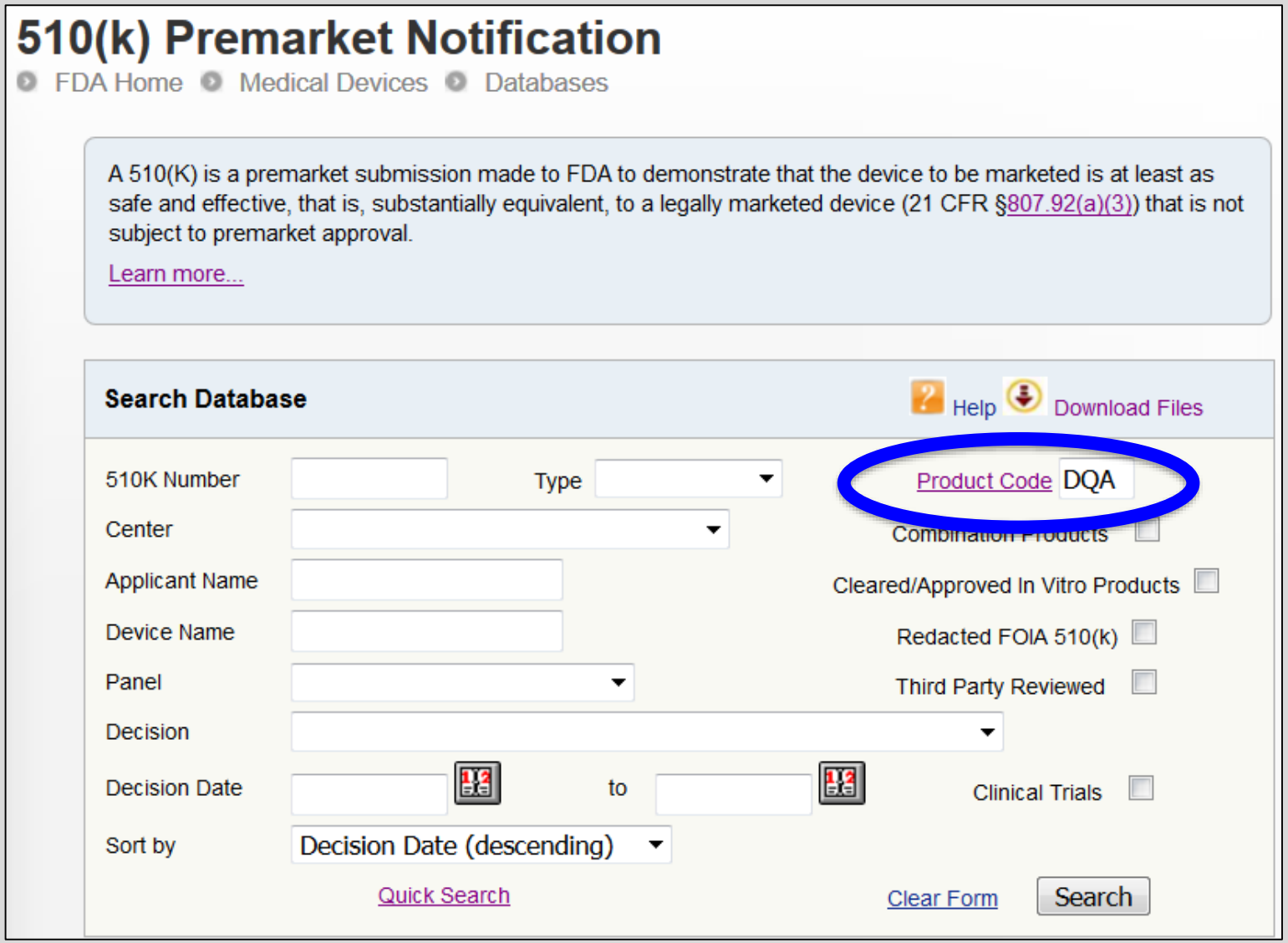
The Five 510(k) How To's

1. How to determine the appropriate regulatory pathway
2. **How to** identify an appropriate predicate device
3. How to prepare a 510(k) submission
4. How to demonstrate substantial equivalence
5. How to legally market a 510(k) cleared device

How To #2:
Identifying a Predicate Device

- Search the Internet
- Search FDA's public Establishment Registration and Device Listing database
- Search FDA's public 510(k) database

Predicate Device Search



Predicate Device Search

510(k) Premarket Notification

FDA Home ● Medical Devices ● Databases

1 to 100 of 500 Results *
ProductCode: *dqa* **Decision Date To:** *03/29/2018*

1 2 3 4 5 >

Results per Page 100

Export to Excel | Download Files | More About 510(k)

Device Name	Applicant	510(K) Number	Decision Date
Wrist Pulse Oximeter	Beijing Choice Electronic Technology Co.	K172366	03/16/2018
Athena Gtx Device Management Suite (Adms	Athena Gtx	K173203	03/14/2018
Tempus Pro Patient Monitor	Remote Diagnostic Technologies Ltd.	K173768	01/10/2018
V10	Mediana Co., Ltd.	K170497	12/15/2017
The Nellcor Pulse Oximetry Monitor Inter	Covidien	K172482	12/15/2017
Masimo Root Monitoring System And Access	Masimo Corporation	K171121	11/17/2017
Umec Series Patient Monitors (Including	Shenzhen Mindray Bio-medical Electronics	K171901	11/15/2017
[illegible]	Philips Medical Systems	K172226	11/09/2017
Fingertip Pulse Oximeter	Shenzhen Jumper Medical Equipment Co., L	K170965	11/03/2017
Monitor B125, Monitor B105	Ge Medical Systems (China) Co., Ltd.	K171580	11/01/2017
Smartlinx Vitals Plus Nibp Module, Smart	Capsule Technologie, Sas	K171751	10/24/2017
[illegible]	Philips Medizin Systeme Boeblingen Gmbh	K171801	10/06/2017
Finger Pulse Oximeter	Shenzhen Fitfaith Technology Co.,ltd	K163135	09/19/2017

Predicate Device Search Results

Characteristic	Our Proposed Device	K172366	K170965	K163135
Intended Use	Non-invasive, spot-check of SpO2 and pulse rate.	Non-invasive, spot-check of SpO2 and pu rat	Non-invasive, spot-check of SpO2 and pu rat	Non-invasive, spot-check of SpO2 and pulse rate.
Application Site	Fingertip	Wris	Finge	Fingertip
Submission Type	N/A	Tra	Sp	Traditional
510(k) Summary or Statement	N/A	510(k) Summary	510(k) Statement	510(k) Summary

Public Information about 510(k)s

- Search FDA's public 510(k) database
- Consider a Freedom of Information Act (FOIA) Request
- Consider contacting the 510(k) owner and/or searching their website

References:

- CDRH FOIA
- CDRH FOI Reference Sheet

The Five 510(k) How To's

1. How to determine the appropriate regulatory pathway
2. How to identify an appropriate predicate device
3. **How to** prepare a 510(k) submission
4. How to demonstrate substantial equivalence
5. How to legally market a 510(k) cleared device

How To #3:
Preparing a 510(k) Submission

- Format for Traditional and Abbreviated 510(k)s
- Refuse to Accept Policy for 510(k)s Guidance
- 510(k) Forms
- eCopy Program

510(k) Submission Reminders

- Ensure information is complete and organized
- Clearly identify basic 510(k) requirements
- Be consistent throughout the submission
- Follow current applicable guidance documents and device specific checklists

The Five 510(k) How To's

1. How to determine the appropriate regulatory pathway
2. How to identify an appropriate predicate device
3. How to prepare a 510(k) submission
4. **How to** demonstrate substantial equivalence
5. How to legally market a 510(k) cleared device

How To #4:
Demonstrating Substantial Equivalence

- Utilize the 510(k) Decision-Making Flowchart
- Search for relevant:
  - FDA Guidance Documents (cross-cutting and device specific)
  - FDA Recognized Consensus Standards (cross-cutting and device specific)

Pulse Oximeter Guidance Document

Pulse Oximeters - Premarket Notification Submissions [510(k)s]

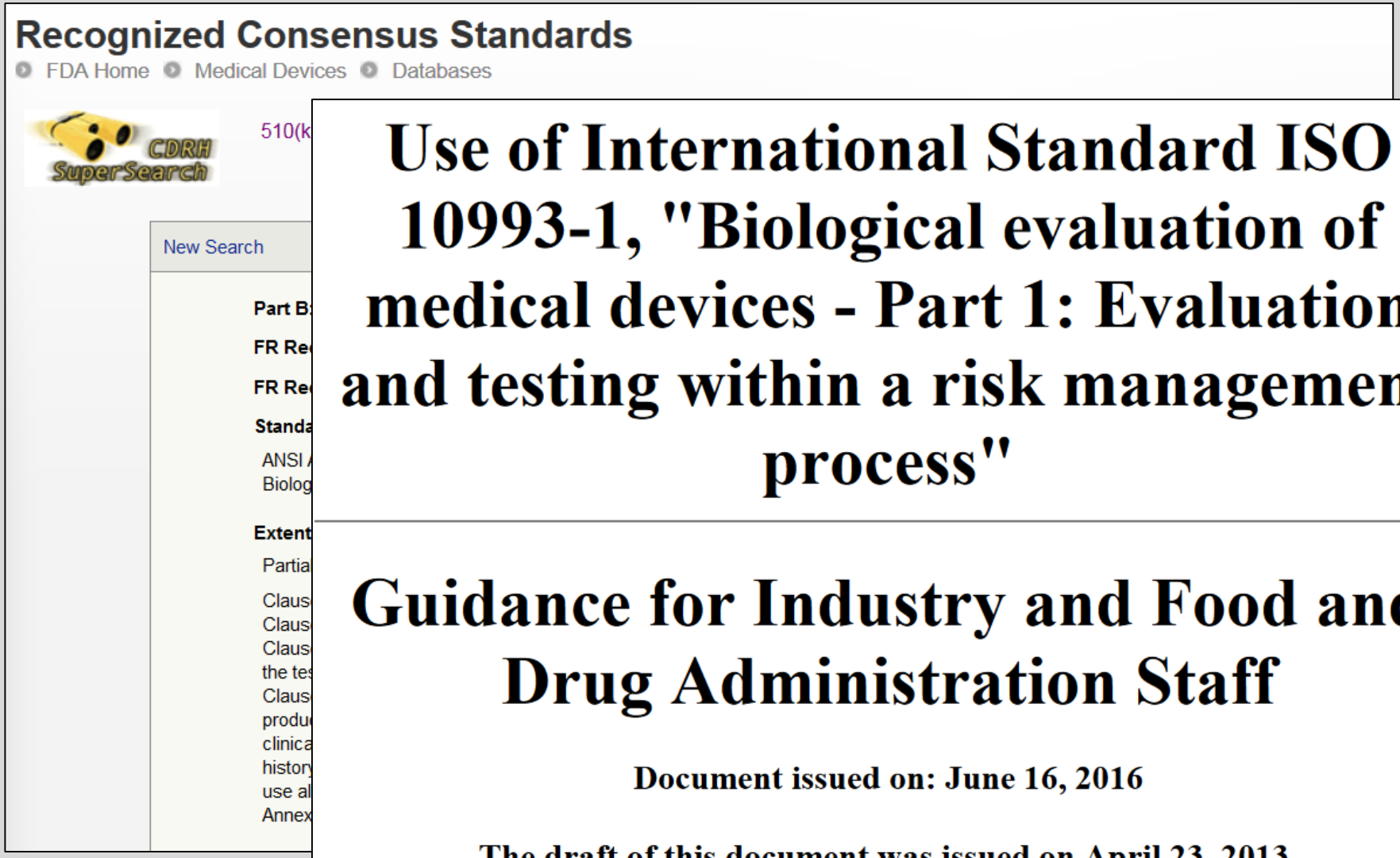
Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 4, 2013

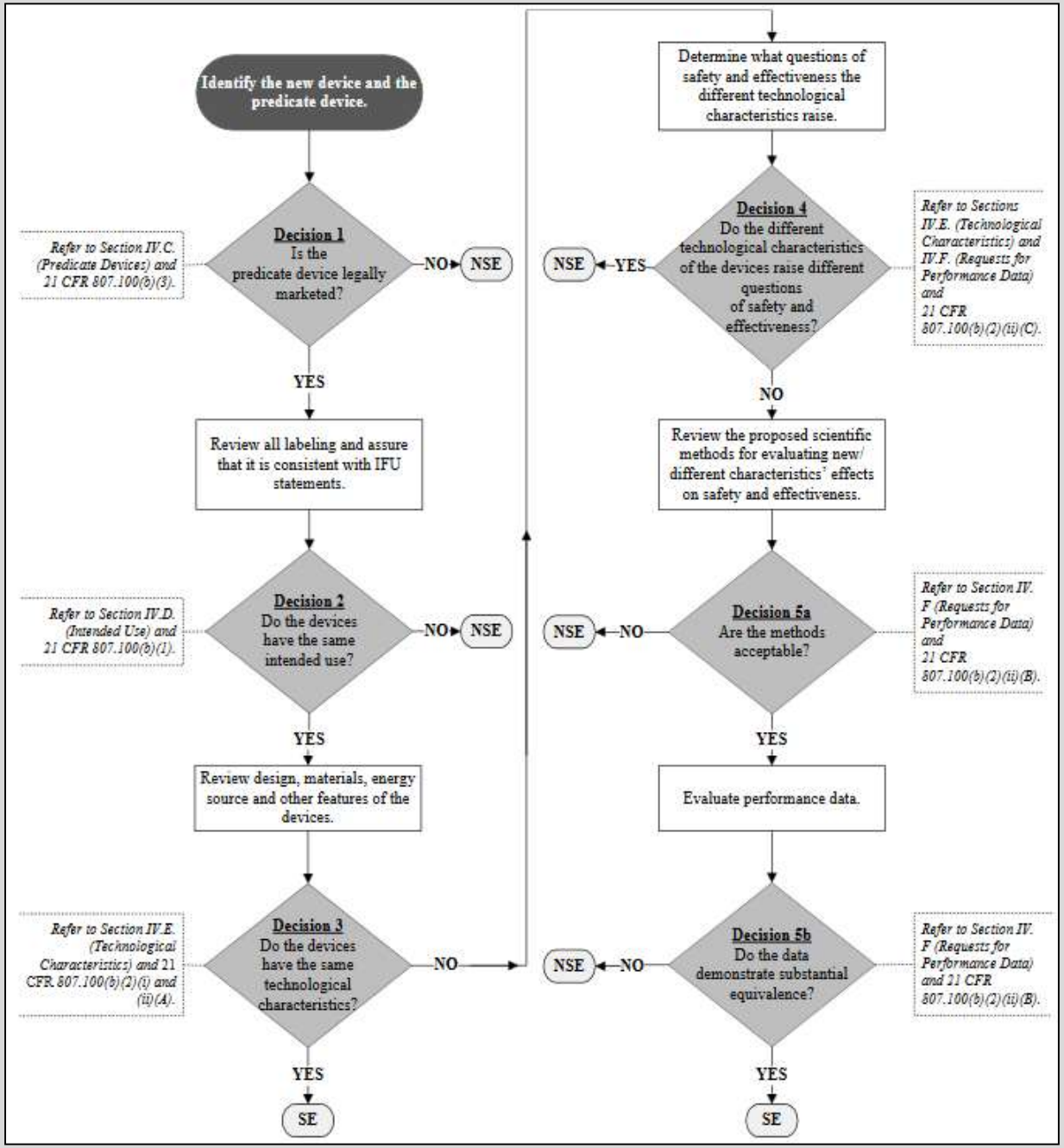
This document supersedes Non-invasive Pulse Oximeter General Guidance Document, September 7, 1992

The draft of this document was issued on July 19, 2007.

Standards and Guidance



510(k) Decision-Making Flowchart

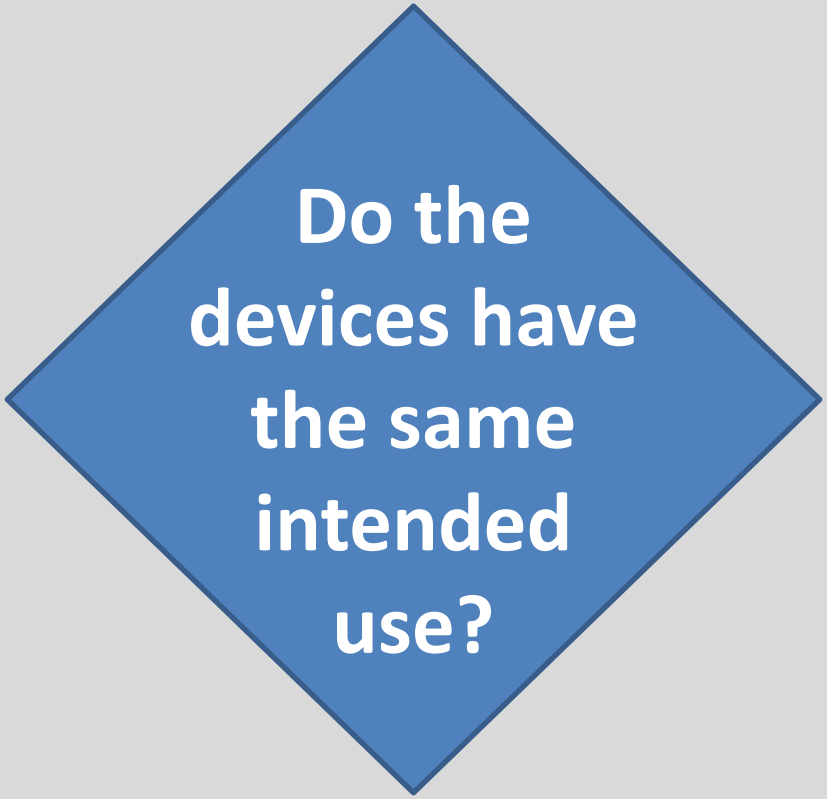


Flowchart: Decision Point 1

Flowchart: Decision Point 1

Characteristic	Proposed Device	Predicate Device
Company Name	Golden Gate Equipment Co.	Shenzhen Fitfaith Technology Co., Ltd.
Trade Name	Fingertip Pulse Oximeter (Models: ABC, XYZ)	Fingertip Pulse Oximeter (Models: A300, A310, M110, M120, M130, M150, M160, M170, M230)
Product Code	DQA	Same
Regulation	21 CFR 870.2700	Same
Device Class	2	Same
510(k) Clearance	TBD	K163135

Flowchart: Decision Point 2



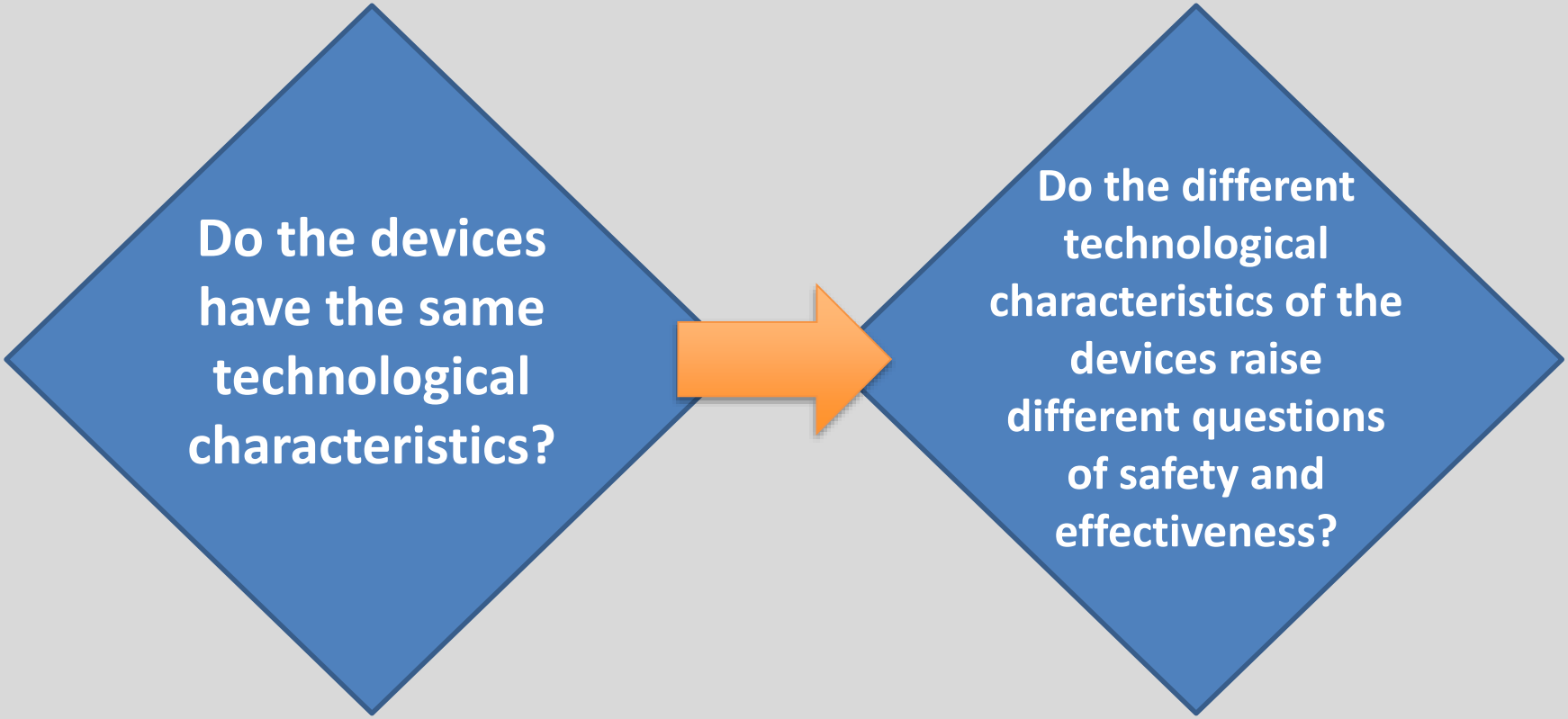
Flowchart: Decision Point 2

Characteristic	Proposed Device	Shenzhen Fitfaith Fingertip Pulse Oximeter (K163135)
Intended Use	Non-invasive measurement of SpO2 and pulse rate	Same
Indications for Use		
Prescription Use (Rx) or Over the Counter (OTC)	Rx Only	Same
Application Site	Fingertip	Same
Spot-check or Continuous Monitoring	Spot-check	Same
Patient Population	Adults and Pediatrics	Same

Flowchart: Decision Point 2 (Cont'd)

Characteristic	Proposed Device	Shenzhen Fitfaith Fingertip Pulse Oximeter (K163135)
Indications for Use Cont'd		
Stand-alone device or Multi-parameter module	Stand-alone	Same
Environment of Use	Home and hospital environment	Same
Single Use or Multi-Use	Multi-Patient Use	Single Patient Use

Flowchart: Decision Points 3 & 4



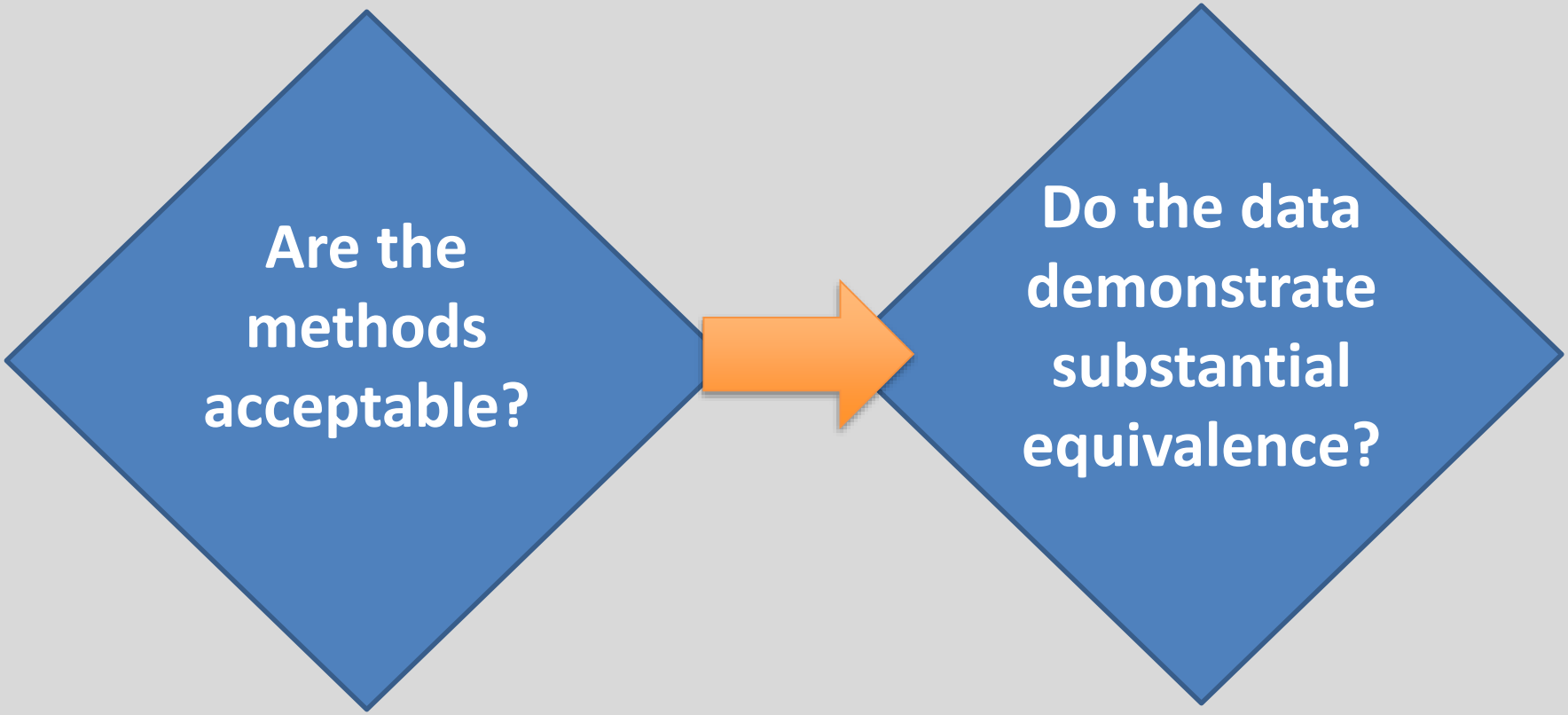
Flowchart: Decision Point 3 & 4

Technological Characteristic	Proposed Device	Shenzhen Fitfaith Fingertip Pulse Oximeter (K163135)
Theory of Operation	Functional oxygen saturation	Same
Alarms	• Visual and sound alarm function • Pulse rate sound indication	Same
Sterile or Non-Sterile	Non-Sterile	Same
Patient Contacting Materials	Enclosure: PC/ABS Plastic Clip: Silica gel	Enclosure: ABS Clip: Same
Data Transfer	USB cable for data transfer	No cable or data transfer capability

Flowchart: Decision Point 3 & 4 (cont'd)

Technological Characteristic	Proposed Device	Shenzhen Fitfaith Fingertip Pulse Oximeter (K163135)
Measurement Wavelength	Red: 660 nm Infrared: 940 nm	Red: 660 nm ± 3nm Infrared: 905 nm ± 5 nm
Power	2 AAA alkaline batteries	Same
Accuracy	SpO2: ± 2% (70% ~ 100%) Pulse Rate: ±2 bpm	Same
Operating / Storage Temperature	Operating: 10◦C ~ 35◦C Storage: -10◦C ~ +50◦C	Operating: 5◦C ~ 40◦C Storage: -20◦C ~ +55◦C
Display Information	SpO2, Pulse Rate, Battery Indicator	SpO2, Pulse Rate, Battery Indicator, Perfusion Index (PI)

Flowchart: Decision Points 5 a & b



Flowchart: Decision Point 5 a & b

Performance Testing	Shenzhen Fitfaith Fingertip Pulse Oximeter (K163135)	Reference(s)
Electrical Safety	Complies with IEC 60601-1	Guidance Pulse Oximeters – Premarket Notification Submission [510(k)s]
Electromagnetic Compatibility (EMC)	Complies with IEC 60601-1	
Software Level of Concern	Moderate	• Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices • General Principles of Software Validation; Final Guidance for Industry and FDA Staff • Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices

Flowchart: Decision Point 5 a & b (Cont'd)

Performance Testing	Shenzhen Fitfaith Fingertip Pulse Oximeter (K163135)	Reference(s)
Cleaning, Disinfection and Sterilization	Not applicable, Single Use	Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
Biocompatibility	Complies with ISO 10993-1	Use of International Standard ISO- 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
Clinical Validation	Complies with ISO 80601	Guidance Pulse Oximeters – Premarket Notification Submission [510(k)s]

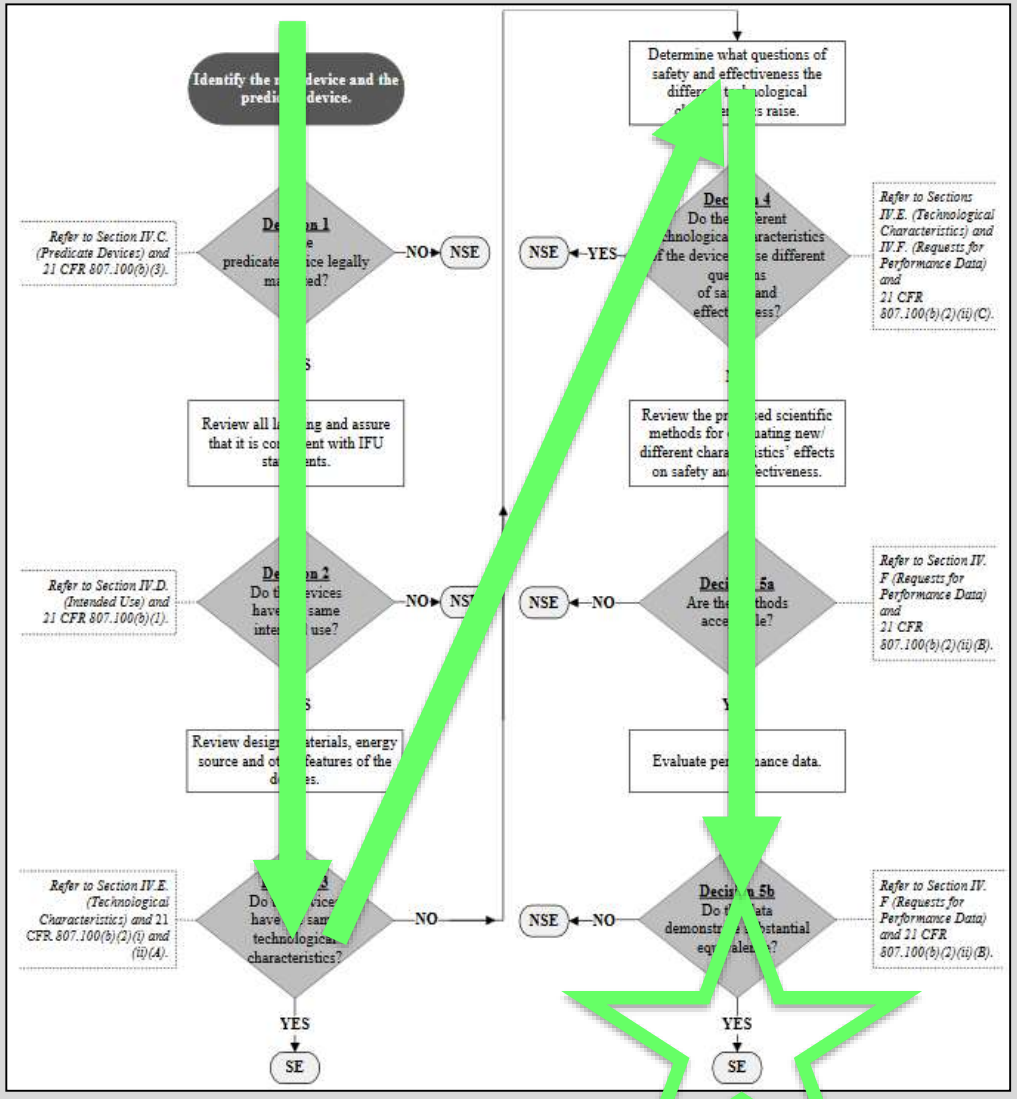
Requesting FDA Feedback

- Consider a **Pre-Submission** (e.g., Pre-Sub for a 510(k))
  - Feedback can be provided as a formal written response or meeting (in-person or teleconference)
  - Written feedback from FDA by day 70 or 5 days prior to a scheduled meeting

References:

- FDA Guidance - Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff [Pre-Sub for a 510(k) is under Appendix 1.C]
- *CDRH Learn Modules Available*

Substantial Equivalence Determination



The Five 510(k) How To's

1. How to determine the appropriate regulatory pathway
2. How to identify an appropriate predicate device
3. How to prepare a 510(k) submission
4. How to demonstrate substantial equivalence
5. **How to** legally market a 510(k) cleared device

How To #5:
Legally Marketing a 510(k) Cleared Device

- Establishment Registration and Device Listing
- Compliance with the Quality System Regulation (21 CFR 820)
- Modifications to a 510(k) cleared device

Modifications to 510(k) Cleared Devices

- A new 510(k) is needed when a change, or the sum of the incremental changes "could significantly affect the safety or effectiveness of the device" (21 CFR 807.81(a)(3))

- Changes to the following may require a new 510(k):
  - Intended Use
  - Design
  - Materials
  - Sterilization Method

References:

- Is a new 510(k) required for a modification to the device?
- Deciding When to Submit a 510(k) for a Change to an Existing Device
- Deciding When to Submit a 510(k) for a Software Change to an Existing Device

Addition of Bluetooth Technology

Proposed Modification	Modify data transfer mechanism from USB cable to Bluetooth Technology
Is a 510(k) required?	**Yes**
510(k) Submission Type	**May be eligible for a Special 510(k)**

Case Study 'How To' Wrap Up

✓	Determined the appropriate regulatory pathway
✓	Identified an appropriate predicate device
✓	Learned how to prepare our 510(k) submission
✓	Determined how we wanted to demonstrate substantial equivalence
✓	Discussed how to legally market our 510(k) cleared device

Questions

Please evaluate this session:

surveymonkey.com/r/DEV-D1S04

Your Call to Action

- Remember the Five 510(k) How To's
- Be diligent in identifying and comparing your proposed device to a predicate device
- Utilize the 510(k) Decision-Making Flowchart
- Identify and become familiar with relevant resources and references


FDA
U.S. FOOD & DRUG
ADMINISTRATION