A 510(k) Case Study – Demonstrating Substantial Equivalence for a Foley Catheter

FDA Small Business
Regulatory Education for Industry (REdI)
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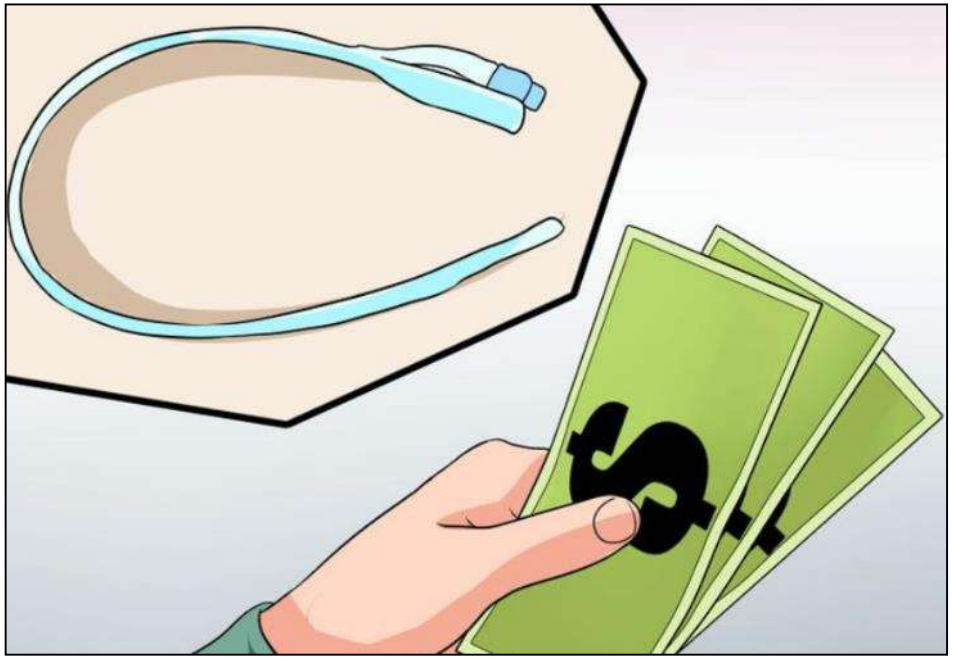
1.45 billion catheters were sold globally in 2014.



Learning Objectives

1. Determine the appropriate regulatory pathway for a Foley Catheter

2. Identify key elements for demonstrating substantial equivalence when preparing a 510(k) submission for a Foley Catheter

3. Discuss how to use the 510(k) Decision-Making Flowchart when demonstrating substantial equivalence for a new Foley Catheter

Presentation Outline

- Regulatory Pathway for Foley Catheters
- Key Elements of Substantial Equivalence
- 510(k) Decision-Making Flowchart Walk Through
- Questions

Presentation Outline

- **Regulatory Pathway for Foley Catheters**
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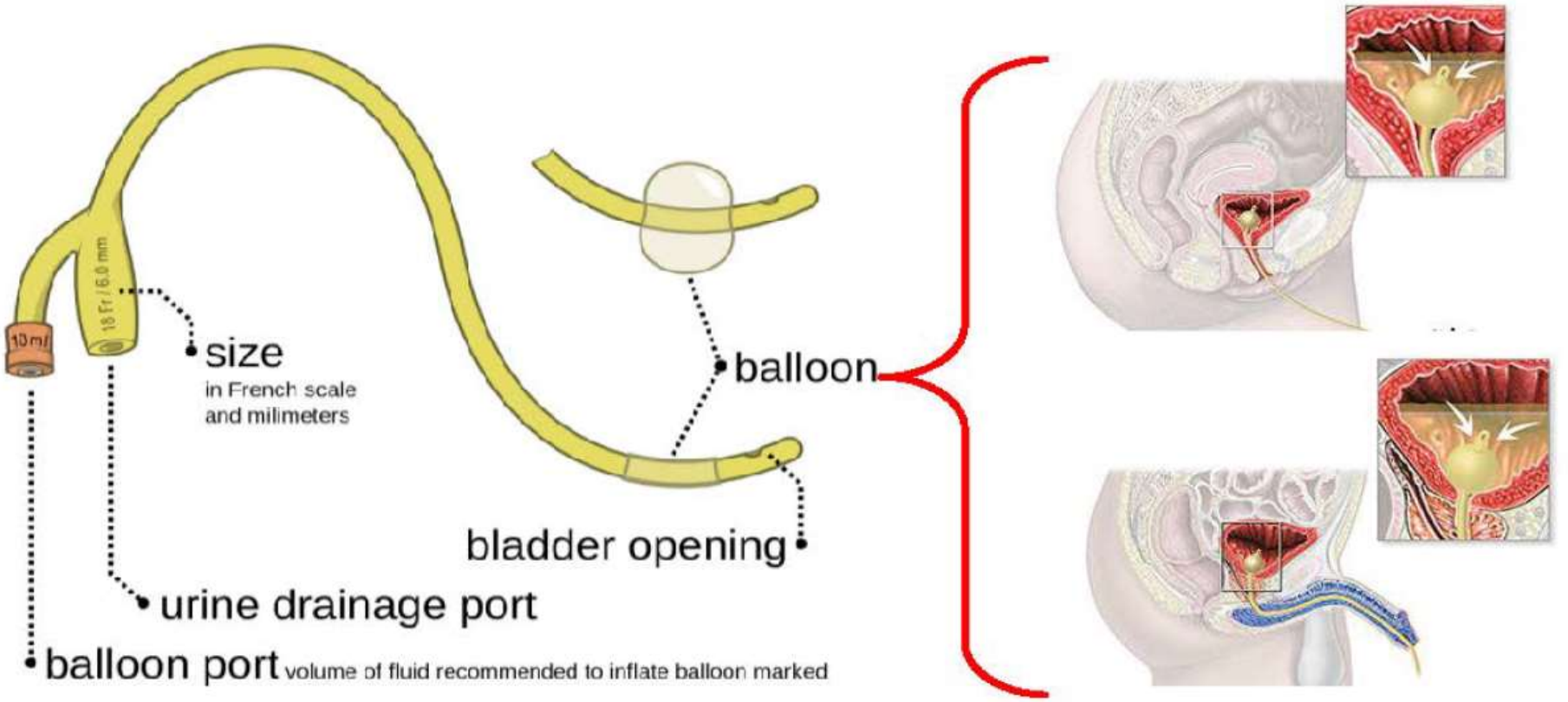
Foley Catheter

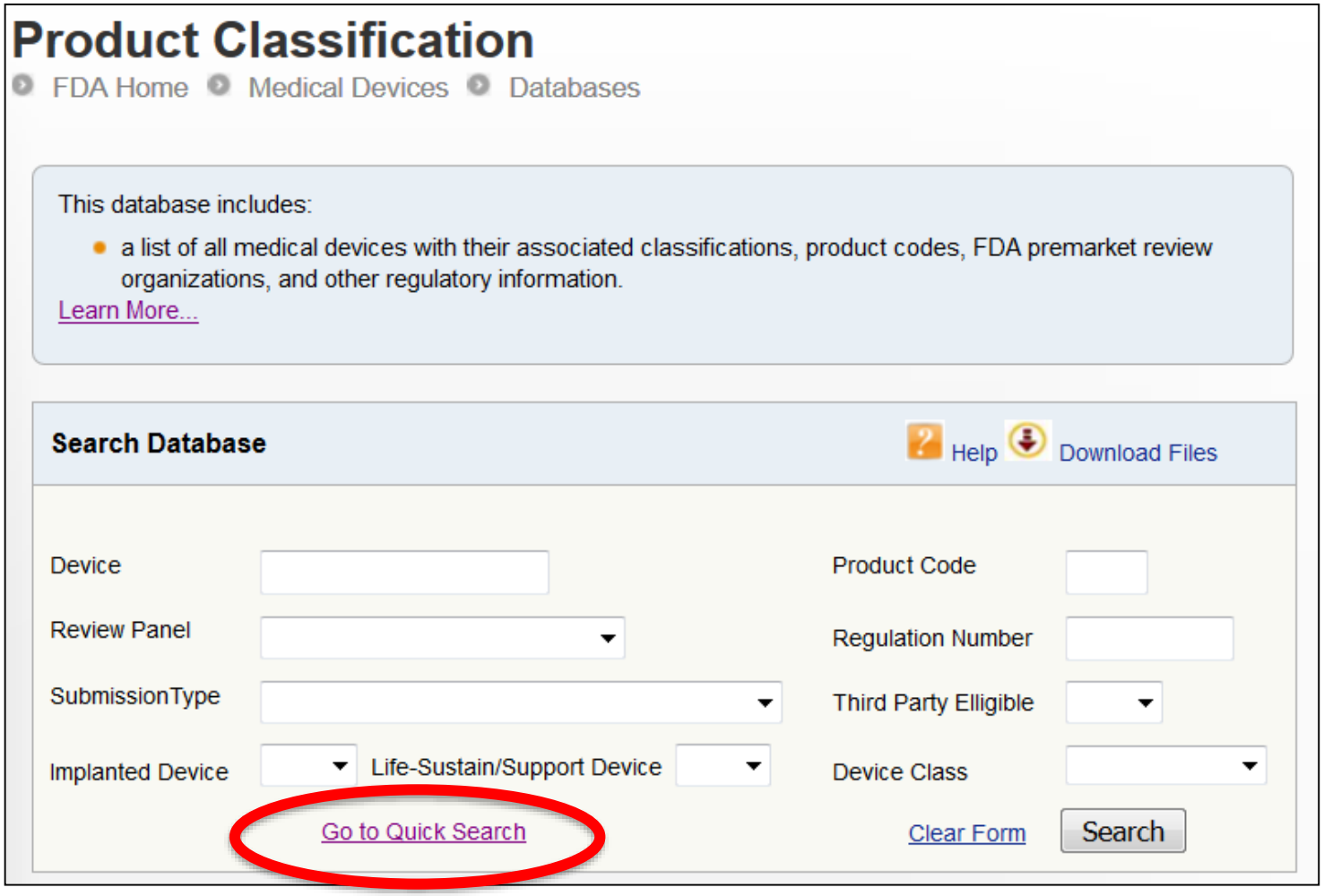


Poll Question

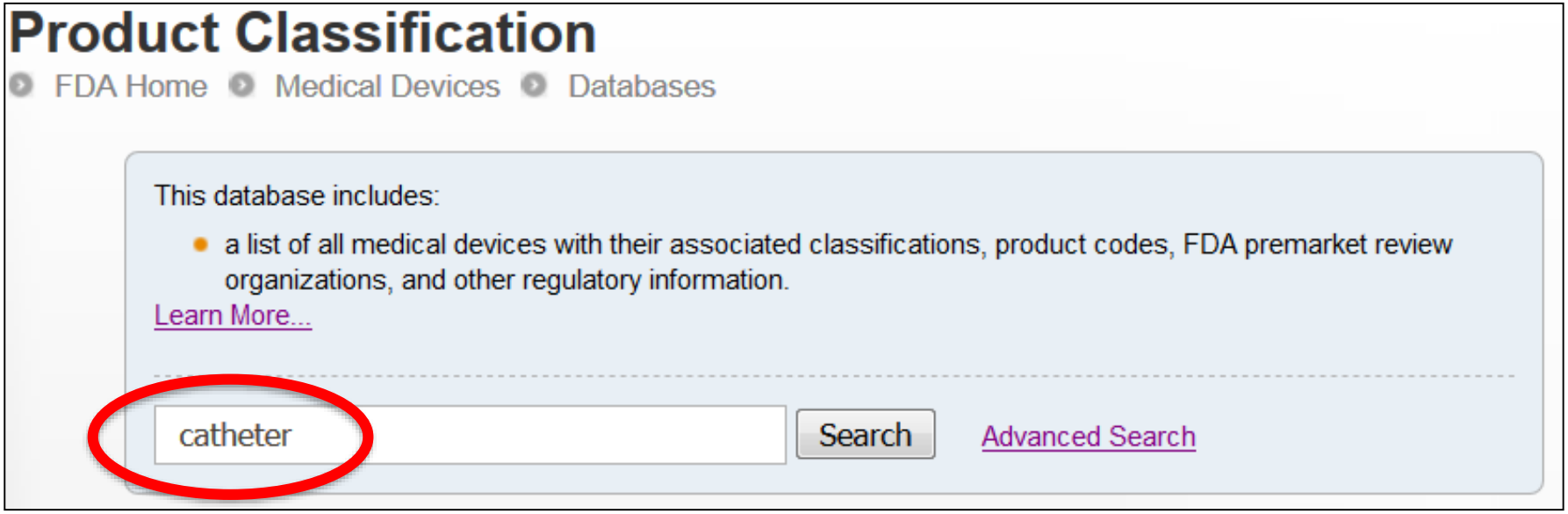
How familiar are you with searching for product classifications?

A. Very
B. A little
C. Not at all

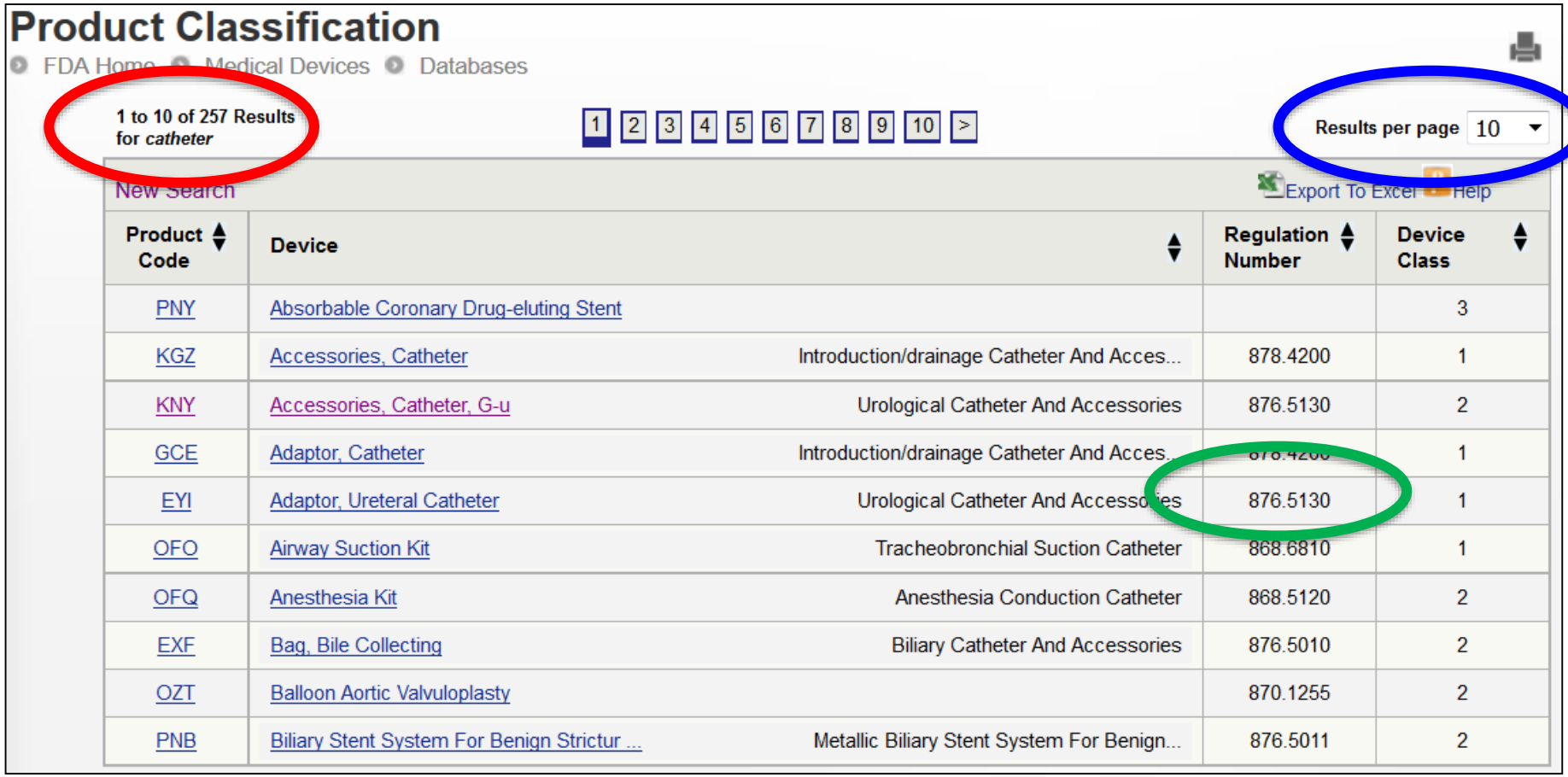
Example: Product Classification Database



Example: Product Classification Database



Example: Product Classification Database



Product Classification

FDA Home › Medical Devices › Databases

1 to 10 of 257 Results for *catheter*

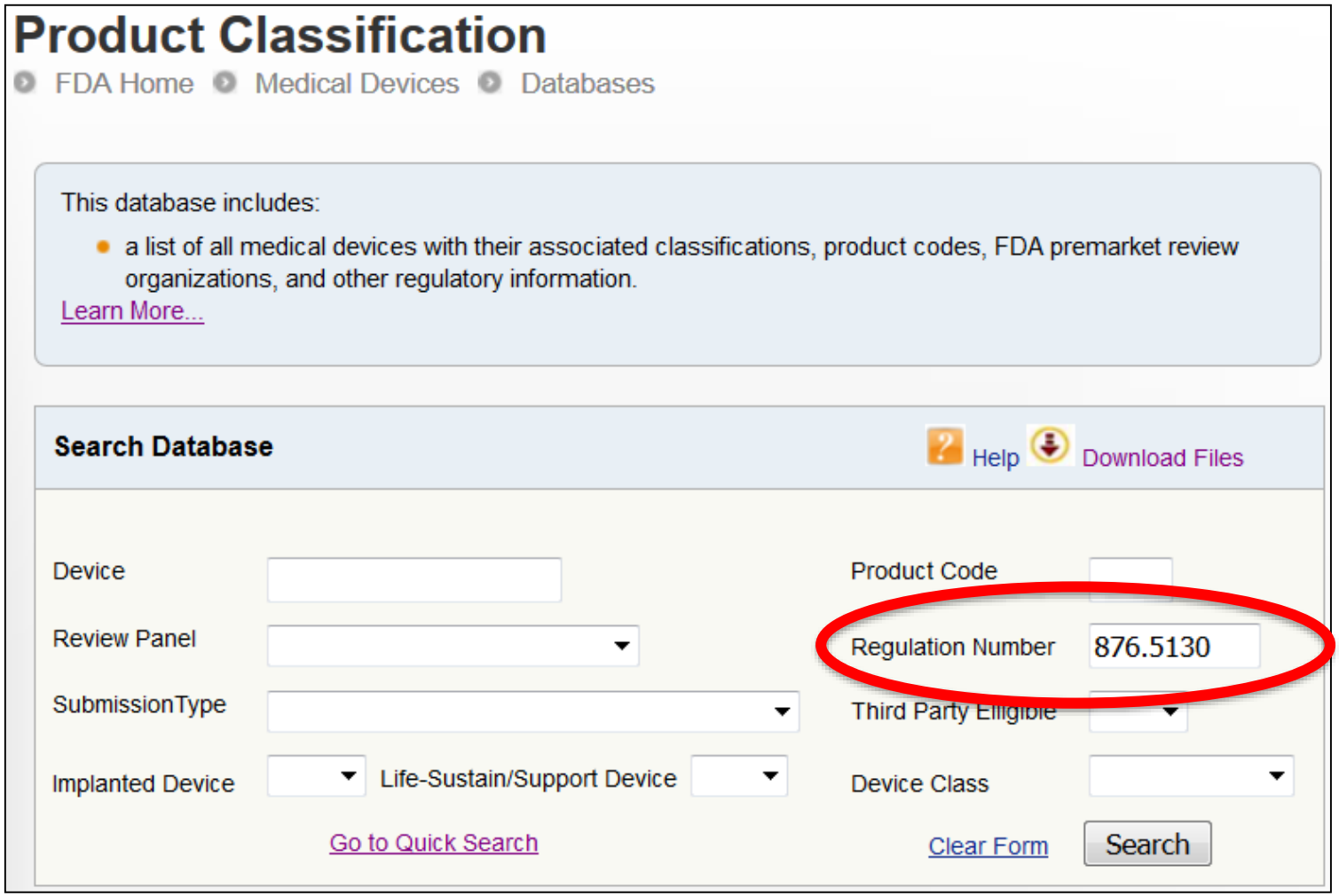
1 2 3 4 5 6 7 8 9 10 >

Results per page 10

New Search | Export To Excel | Help

Product Code	Device		Regulation Number	Device Class
PNY	Absorbable Coronary Drug-eluting Stent			3
KGZ	Accessories, Catheter	Introduction/drainage Catheter And Acces...	878.4200	1
KNY	Accessories, Catheter, G-u	Urological Catheter And Accessories	876.5130	2
GCE	Adaptor, Catheter	Introduction/drainage Catheter And Acces...	[illegible]	1
EYI	Adaptor, Ureteral Catheter	Urological Catheter And Accessories	876.5130	1
OFO	Airway Suction Kit	Tracheobronchial Suction Catheter	868.6810	1
OFQ	Anesthesia Kit	Anesthesia Conduction Catheter	868.5120	2
EXF	Bag, Bile Collecting	Biliary Catheter And Accessories	876.5010	2
OZT	Balloon Aortic Valvuloplasty		870.1255	2
PNB	Biliary Stent System For Benign Strictur ...	Metallic Biliary Stent System For Benign...	876.5011	2

Example: Product Classification Database



Product Code	Device		Regulation Number	Device Class
KNY	Accessories, Catheter, G-u	Urological Catheter And Accessories	876.5130	2
EYI	Adaptor, Ureteral Catheter	Urological Catheter And Accessories	876.5130	1
PPA	Bladder Irrigation Kit	Urological Catheter And Accessories	876.5130	2
OHR	Catheter Care Tray	Urological Catheter And Accessories	876.5130	2
EZC	Catheter, Coude	Urological Catheter And Accessories	876.5130	2
FGH	Catheter, Double Lumen Female Urethrographic	Urological Catheter And Accessories	876.5130	2
EZL	Catheter, Retention Type, Balloon	Urological Catheter And Accessories	876.5130	2
EZD	Catheter, Straight	Urological Catheter And Accessories	876.5130	2
EYC	Catheter, Upper Urinary Tract	Urological Catheter And Accessories	876.5130	2
FGF	Catheter, Ureteral Disposable (X-ray)	Urological Catheter And Accessories	876.5130	2
EYB	Catheter, Ureteral, Gastro-urology	Urological Catheter And Accessories	876.5130	2
GBL	Catheter, Ureteral, General & Plastic Surgery	Urological Catheter And Accessories	876.5130	2
GBM	Catheter, Urethral	Urological Catheter And Accessories	876.5130	2
FGI	Catheter, Urethrographic, Male	Urological Catheter And Accessories	876.5130	2
KOD	Catheter, Urological	Urological Catheter And Accessories	876.5130	2
MJC	Catheter, Urological (Antimicrobial) And Accessori ...	Urological Catheter And Accessories	876.5130	2
EYK	Connector, Ureteral Catheter	Urological Catheter And Accessories	876.5130	1
PPB	Foley Catheter Kit (Excludes Hiv Testing)	Urological Catheter And Accessories	876.5130	2
EYJ	Holder, Ureteral Catheter	Urological Catheter And Accessories	876.5130	1
NWQ	Kit, Catheter, External, Male (Excludes Hiv Testin ...	Urological Catheter And Accessories	876.5130	2
NWR	Kit, Catheter, Foley (Excludes Hiv Testing)	Urological Catheter And Accessories	876.5130	2
NWO	Kit, Catheter, Urinary (Exludes Hiv Testing)	Urological Catheter And Accessories	876.5130	2
PPC	Male External Catheterization Kit (Excludes Hiv Te ...	Urological Catheter And Accessories	876.5130	2
EZB	Stylet For Catheter, Gastro-urology	Urological Catheter And Accessories	876.5130	1
EYA	Stylet, Ureteral	Urological Catheter And Accessories	876.5130	1
LJH	System, Irrigation, Urological	Urological Catheter And Accessories	876.5130	2
FCM	Tray, Catheterization, Sterile Urethral, With Or W ...	Urological Catheter And Accessories	876.5130	2
PPD	Universal Drainage Tray	Urological Catheter And Accessories	876.5130	2
PPG	Urinary Drainage Collection Kit	Urological Catheter And Accessories	876.5130	2
PPF	Urinary Irrigation Kit	Urological Catheter And Accessories	876.5130	2

21 CFR 876.5130: Urological Catheter and Accessories

Urological Catheter

Device	Catheter, Retention Type, Balloon
Regulation Description	Urological catheter and accessories.
Regulation Medical Specialty	Gastroenterology/Urology
Review Panel	Gastroenterology/Urology
Product Code	EZL
Premarket Review	Office of Device Evaluation (ODE) Division of Reproductive, Gastro-Renal, and Urological Devices (DRGUD) Urology and Lithotripsy Devices Branch (ULDB)
Submission Type	510(k)
Regulation Number	876.5130
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Recognized Consensus Standard

- 9-44 ASTM F623 -99 (Reapproved 2013)
  Standard Performance Specification for Foley Catheter

Guidance Document

- Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters

Implanted Device?	No
Life-Sustain/Support Device?	No

Third Party Review

- Eligible for *Accredited Persons Program*

Accredited Persons

- Bsi Healthcare
- Center For Measurement Standards Of Industrial
- Dekra Certification B.v.
- Regulatory Technology Services, Llc
- Third Party Review Group, Llc
- Tuv Sud America Inc.

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- **Key Elements of Substantial Equivalence**
- 510(k) Decision-Making Flowchart Walk Through
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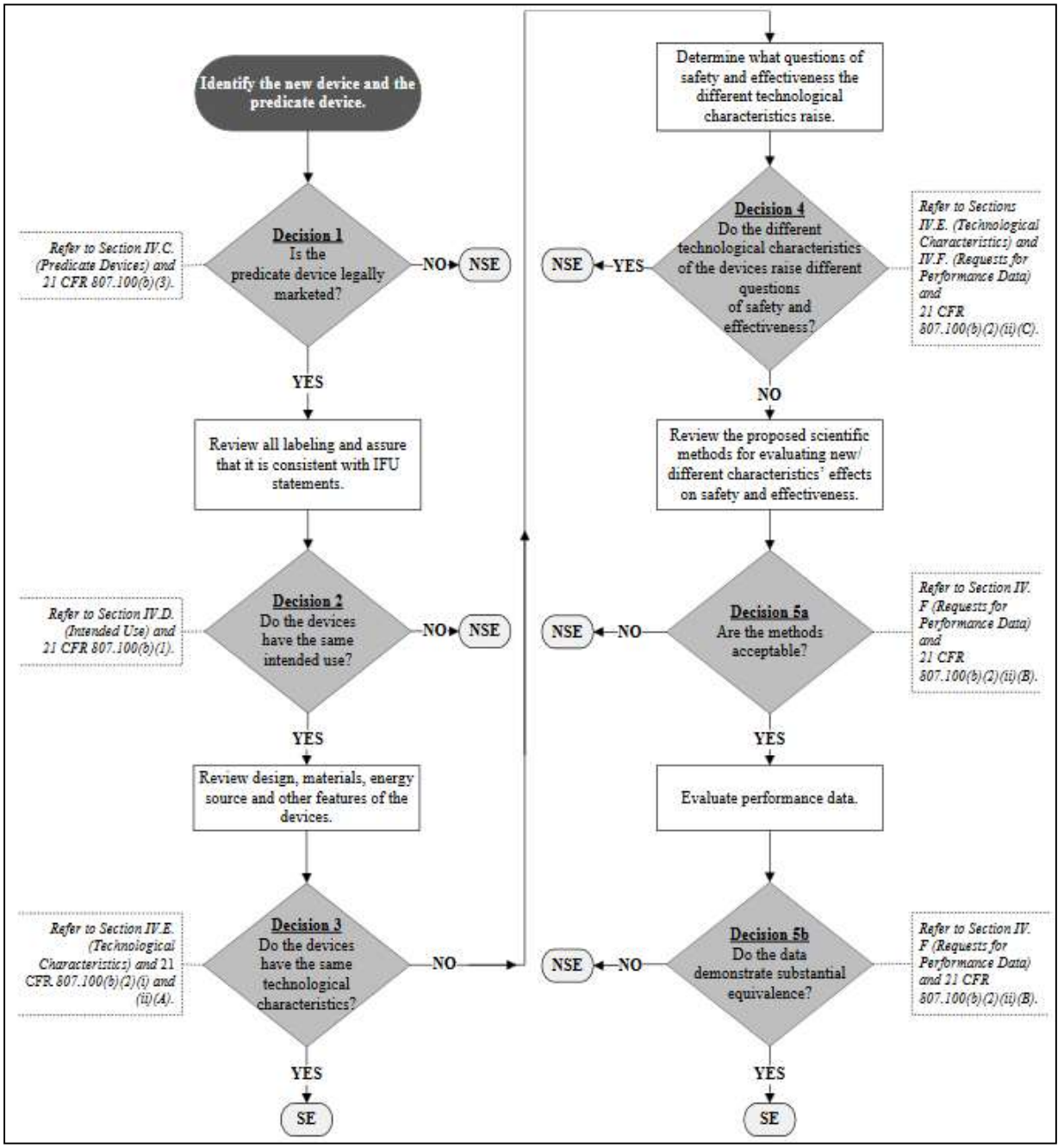
Key Elements of Substantial Equivalence

- **Predicate Device**
- **Intended Use**
- **Technological Characteristics**
- **Performance**

510(k) Decision-Making Flowchart



Key Elements of Substantial Equivalence	Corresponding Decision Point in Flowchart
Predicate Device	1
Intended Use	2
Technological Characteristics	3 & 4
Performance	5 a & b

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Flowchart: Decision Point 1

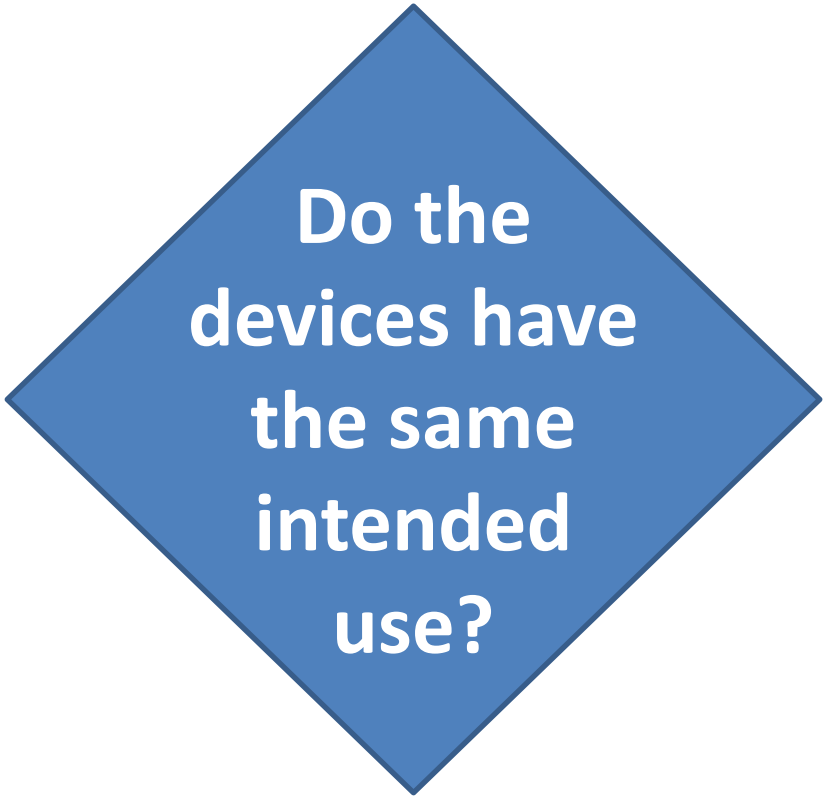
Flowchart: Decision Point 1

Key Element of Substantial Equivalence	Proposed Device	Predicate Device
Predicate Device		
Legally Marketed	TBD	K17XXXX
Classification Name	Catheter, retention type, balloon	Catheter, retention type, balloon
Regulation	21 CFR 876.5130	21 CFR 876.5130
Product Code	EZL	EZL
Class	2	2

Helpful Resources:

- Product Classification Database
- 510(k) Clearance Database
- Freedom of Information Act (FOIA)

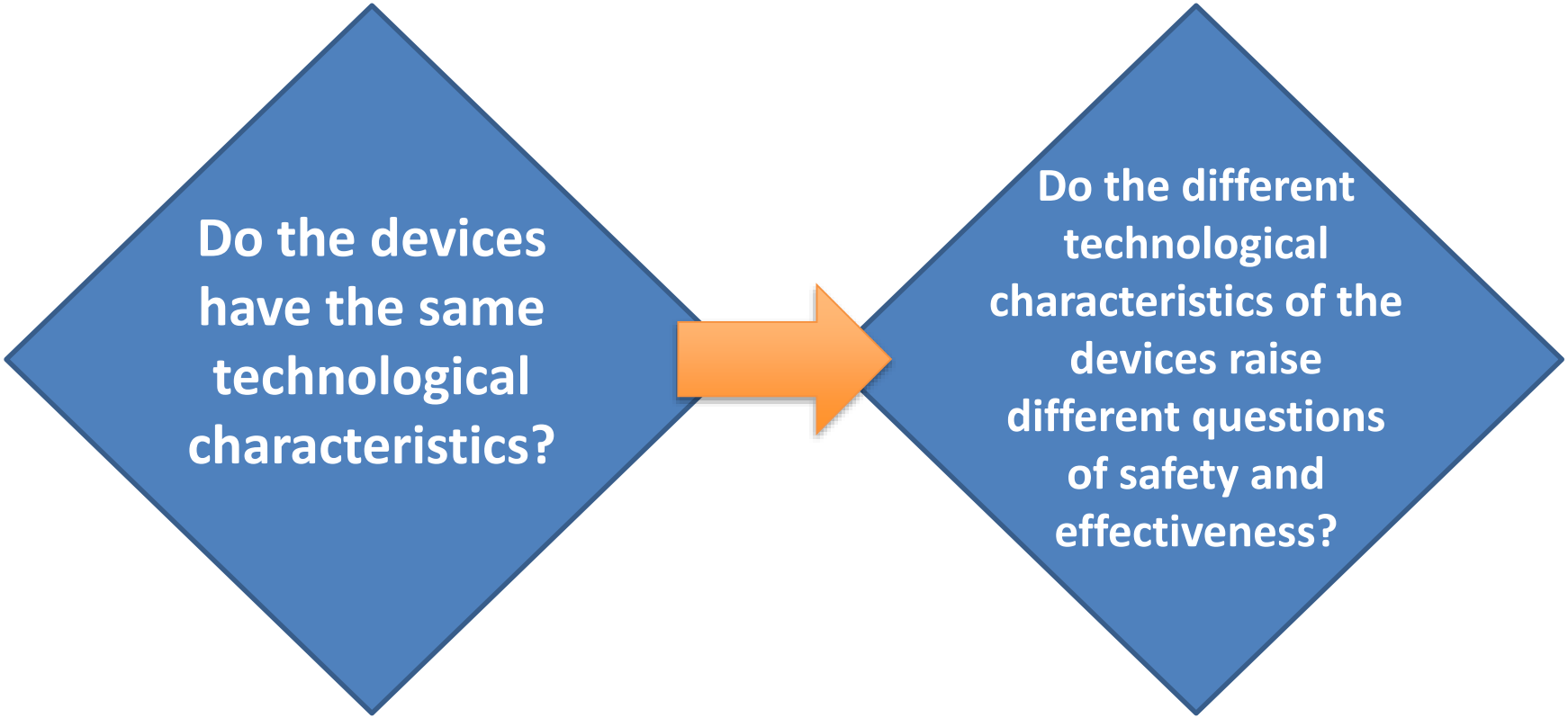
Flowchart: Decision Point 2



Flowchart: Decision Point 2

Key Element of Substantial Equivalence	Proposed Device	Predicate Device
Intended Use	For use in the drainage and/or collection and/or measurement of urine.	Same
Prescription Use (Rx) or OTC	Rx	Same
Patient Population	Adults Only	Adults and Pediatrics
Sterile	Yes	Same
Single Use	Yes	Same
Indwelling time	< 30 days	Same
Balloon Inflation Liquid	Sterile Water	Same
Reprocessed	No	Same

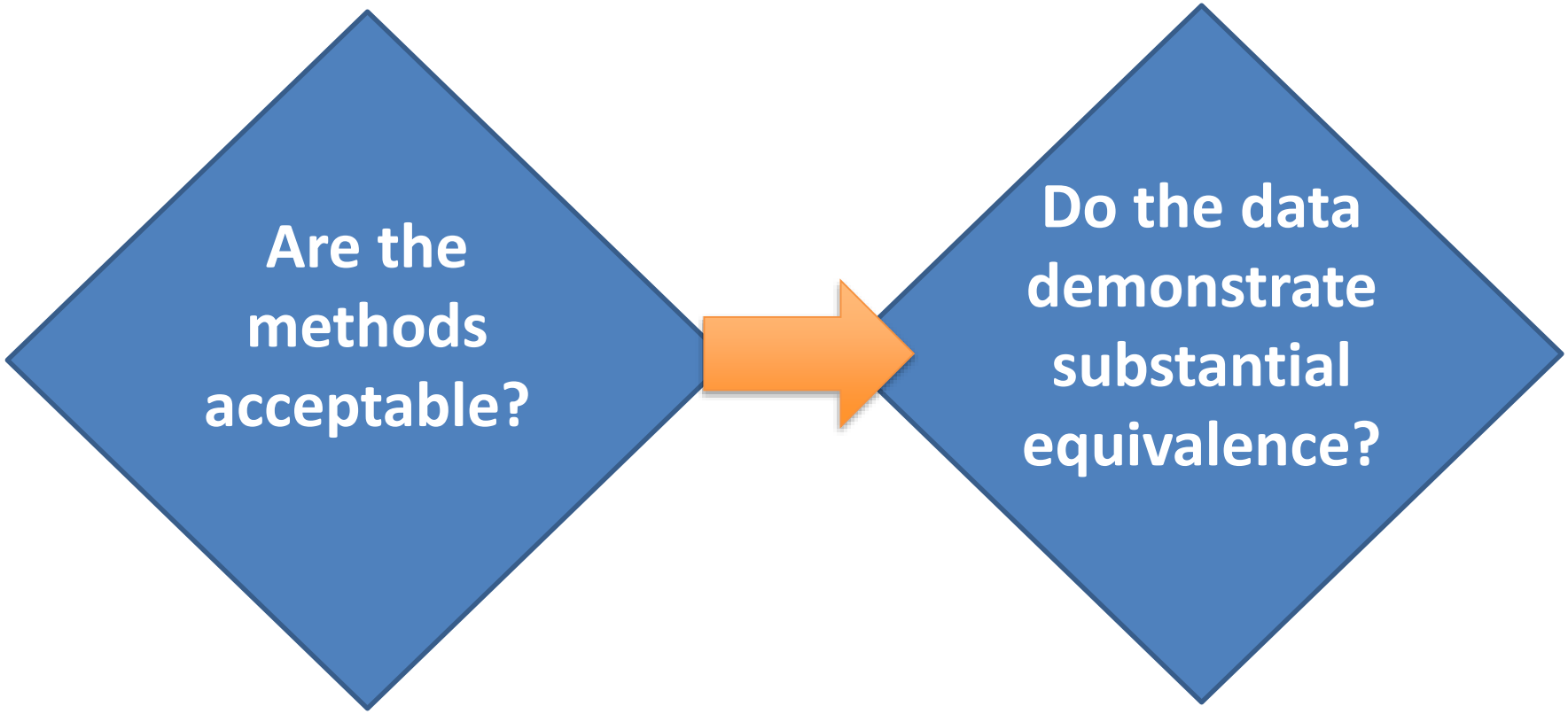
Flowchart: Decision Points 3 & 4



Flowchart: Decision Point 3 & 4

Key Element of Substantial Equivalence	Proposed Device	Predicate Device
Technological Characteristics		
Catheter Type	Two-way Foley Catheter	Two-way and Three-way Foley Catheter
Catheter Size	14 – 18 Fr	8 – 30 Fr
Balloon Size	5 cc	3, 5, 30 and 75 cc
Tip Design	Straight	Straight and Curved "Coude"
Materials		
Catheter	Synthetic Polyisoprene	Natural Rubber Latex
Catheter Coating	Hydrogel Coating	Same
Ink	Black Ink	Same

Flowchart: Decision Points 5 a & b



Flowchart: Decision Point 5 a & b

Key Element of Substantial Equivalence	Resource
Performance	Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters and ASTM F623-99 (2006)
Flow Rate	
Resistance of the balloon to rupture	
Resistance of the inflated balloon to being distorted and pulled through the bladder outlet	
Maintenance of balloon inflation volume	
Manufacturing Tolerances	
Ability of inflated catheter to deflate	
Coefficient of Friction (COF)	

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

Key Element of Substantial Equivalence	Proposed Device	Resource
Performance		
Biocompatibility	Irritation, Sensitization, Cytotoxicity, Acute Systemic Toxicity and Implantation	Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process - Guidance for Industry and Food and Drug Administration Staff
Sterilization	Ethylene Oxide	Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile - Guidance for Industry and Food and Drug Administration Staff
Shelf Life	12 months	ASTM F1980-16

Poll Question

Would the addition of an antimicrobial claim require additional performance testing?

A. Yes
B. No
C. It Depends

Addition of an Antimicrobial Claim

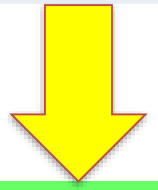
- Catheter, urological (antimicrobial) and accessories (Product Code MJC)

- Clear Labeling (e.g., includes active agent, amount/concentration)

- Additional Testing Required:
  - Chemistry, Pharmacology, Microbiology, etc.
  - Randomized, controlled clinical study to demonstrate decrease in infection rate (e.g., Urinary Tract Infection (UTI))

Foley Catheter Case Study Wrap-up

Key Elements of Substantial Equivalence	Corresponding Decision Point in Flowchart	Foley Catheter Case Study Decision
Predicate Device	1	Yes
Intended Use	2	Yes
Technological Characteristics	3 & 4	No
Performance	5 a & b	Yes



Ready to Submit 510(k)

Requests for FDA Feedback

- Consider the **Pre-Submission Program**
  - Method to obtain feedback from the FDA
  - Typically for unique situations (e.g. need for clinical data)
  - Request either a formal written response, meeting, or teleconference to address your questions

References:

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

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- **Questions**

Questions

Please complete the session survey:

surveymonkey.com/r/DEV-D1S06

Call to Action

- Ensure you determine the appropriate regulatory pathway for a new device
- Be diligent in identifying and comparing the characteristics of a new device to a predicate device
- Utilize the 510(k) Decision-Making Flowchart


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