A Case Study on Medical Device Determination and Product Classification

FDA Small Business
Regulatory Education for Industry (REdI)
Boston, MA
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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

Poll Question

Which of the following products are regulated as medical devices?

A. 1 and 2
B. 1 and 3
C. 3 Only
D. All of the Above

1

Adult Diaper

2

Baby Diaper

3

Blood Glucose Meter

4

Cotton Swab

Poll Question

Which of the following products are regulated as medical devices?

~~A. 1 and 2~~

B. 1 and 3

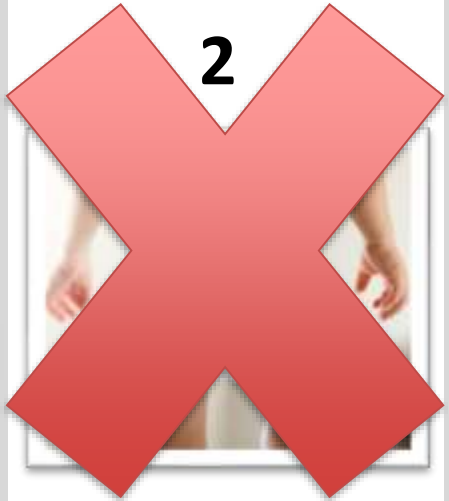
~~C. 3 Only~~

~~D. All of the Above~~

1

Adult Diaper

2

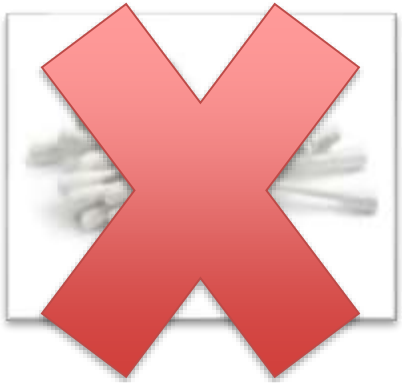


Baby Diaper

3

Blood Glucose Meter

4



Cotton Swab

Learning Objectives

- Define what is a medical device
- Explain how medical devices are classified
- Discuss the different regulatory requirements for medical devices
- Walk through a case study example for device determination and product classification

Outline

1. Does my product meet the definition of a medical device?

2. How would my product be classified?

3. What regulatory requirements apply to my medical device?

4. How can I obtain additional assistance?

Outline

1. **Does my product meet the definition of a medical device?**
2. How would my product be classified?
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Medical Device Defined

Section 201(h) of the Food, Drug & Cosmetic Act defines a medical device as:

- intended for use in the **diagnosis** of disease or other conditions, or in the **cure**, **mitigation**, **treatment**, or **prevention of disease** in man, or
- intended to **affect the structure or any function** of the body

Medical Device Defined

– and does **not** achieve its principal intended purpose by **chemical action** or by being **metabolized.**

– The term "device" does not include software functions excluded pursuant to section 520(o).

Define Your Medical Device

- What is the **intended use** of your device?
- What **claims** do you intend to make?
- How does your device **function**?

Resources:

- Is the Product A Medical Device?
- Device – Not a Device

Defining Your Intended Use is Key!

- Clearly state the general purpose of the device or its function
- Further describe:
  - The disease or condition the device will diagnose, treat, prevent, cure, or mitigate
  - The intended patient population

Outline

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Device Risk

Class

Extent of Regulatory Controls

Device Risk

Class

Extent of Regulatory Controls

Classes of Medical Devices

Class	Risk	Potential Harm	Regulatory Controls	Submission Type or Exemption	Percent Devices in Class*
I					35%
II					53%
III					9%

*3% of devices are Unclassified

Classes of Medical Devices

Class	Risk	Potential Harm	Regulatory Controls	Submission Type or Exemption	Percent Devices in Class*
I	Lowest	Present minimal potential for harm			35%
II	Moderate	Higher risk than Class I devices			53%
III	Highest	Sustain or support life, are implanted, or present potential unreasonable risk of illness or injury			9%

*3% of devices are Unclassified

Outline

1. Does my product meet the definition of a medical device?

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Device Risk

Class

Extent of Regulatory Controls

What are “Regulatory Controls”

- Apply to a particular device type
- Describe the appropriate level of regulatory oversight to ensure reasonable safety and effectiveness
- Generally broad, but may be specific

Resource:

- Regulatory Controls

Classes of Medical Devices

Class	Risk	Potential Harm	Regulatory Controls	Submission Type or Exemption	Percent Devices in Class*
I	Lowest	Present minimal potential for harm	General	510(k) 510(k) Exempt *93% are exempt from 510(k)	35%
II	Moderate	Higher risk than Class I devices	General and Special (if available)	510(k) 510(k) Exempt	53%
III	Highest	Sustain or support life, are implanted, or present potential unreasonable risk of illness or injury	General and PMA	PMA	9%

3% of devices are Unclassified

General Control Examples

Control	Regulation (21 CFR Part)	Brief Description
Adulterated	FDCA 501	Provide device not proper for use
Misbranded	FDCA 502	Provide false or misleading labeling
Labeling	801	Provide information for users
Medical Device Reporting	803	Report device-related injuries and deaths
Establishment Registration	807	Register company with FDA
Device Listing	807	Identify devices with FDA
510(k) Premarket Notification	807	Substantially equivalent to a device legally marketed
Quality System / Good Manu. Practices	820	Ensure safe and effective finished devices

Special Control Examples

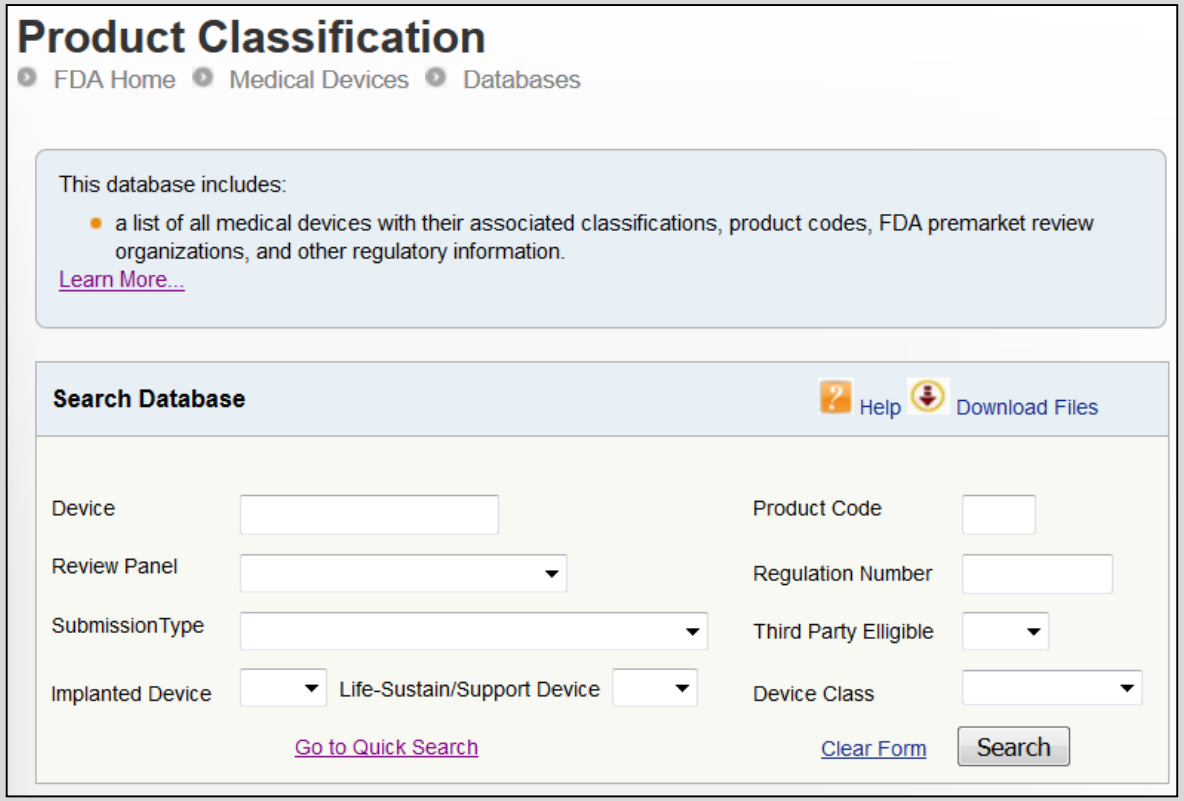
- Design Characteristics or Specifications
- Performance Standards
- Testing
- Special Labeling
- Guidance Documents

Premarket Approval Application (PMA)

- Typically for life supporting or life sustaining devices
- General and Special Controls are insufficient to provide reasonable assurance of safety and effectiveness
- 21 CFR 814

Product Codes

- Three letter codes (e.g., CBK, FRN)
- Used by FDA to identify and track similar medical devices



Resources:

- Guidance: Medical Device Classification Product Codes
- Product Classification Database

Regulations and Product Codes

Same Regulation Number (21 CFR 870.1875);
Four Different Product Codes for Specific Device Types

Device Type	Class	510(k) Exempt?	Product Code
Manual Stethoscope	1	Yes	LDE
Electronic Stethoscope	2	No	DQD
Cranial Sound Monitor	2	No	QBE
Lung Sound Monitor	2	Yes	OCR

Outline

1. Does my product meet the definition of a medical device?
2. How would my device be classified?
3. What regulatory requirements apply to my medical device?
4. **How can I obtain additional assistance?**

Informal Assistance

- Call or email Division of Industry and Consumer Education (DICE)

- Email the Device Determination experts (DeviceDetermination@fda.hhs.gov)

➢ *Responses are not classification decisions and do not constitute FDA clearance or approval for commercial distribution*

Formal Assistance

- Submit a 513(g) Request

- Appropriate when a formal determination or classification is requested or a complex regulatory question is presented

➢ *Responses do not constitute FDA clearance or approval for commercial distribution*

Case Study

3rd Most Common Reason for a Doctor Visit

Back Pain

*From ACA Back Pain Facts and Statistics

Traction Device

Our Intended Use:

To treat low back pain through intermittent and static traction

Case Study Outline

1. Does my product meet the definition of a medical device?

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Case Study Outline

1. **Does my product meet the definition of a medical device?**
2. How would it be classified?
3. What regulatory requirements apply to my medical device?

Is it a Medical Device?

Is our device intended to diagnose, cure, mitigate, treat, or prevent disease in a human?

Yes

Is our device intended to affect the structure or any function of the body not through chemical action?

Yes

Does our device meet the definition of a medical device?

Yes

Case Study Outline

1. Does my product meet the definition of a medical device?

2. **How would it be classified?**

3. **What regulatory requirements apply to my medical device?**

Classification Determination Methods

Most Common

Search for an appropriate product classification

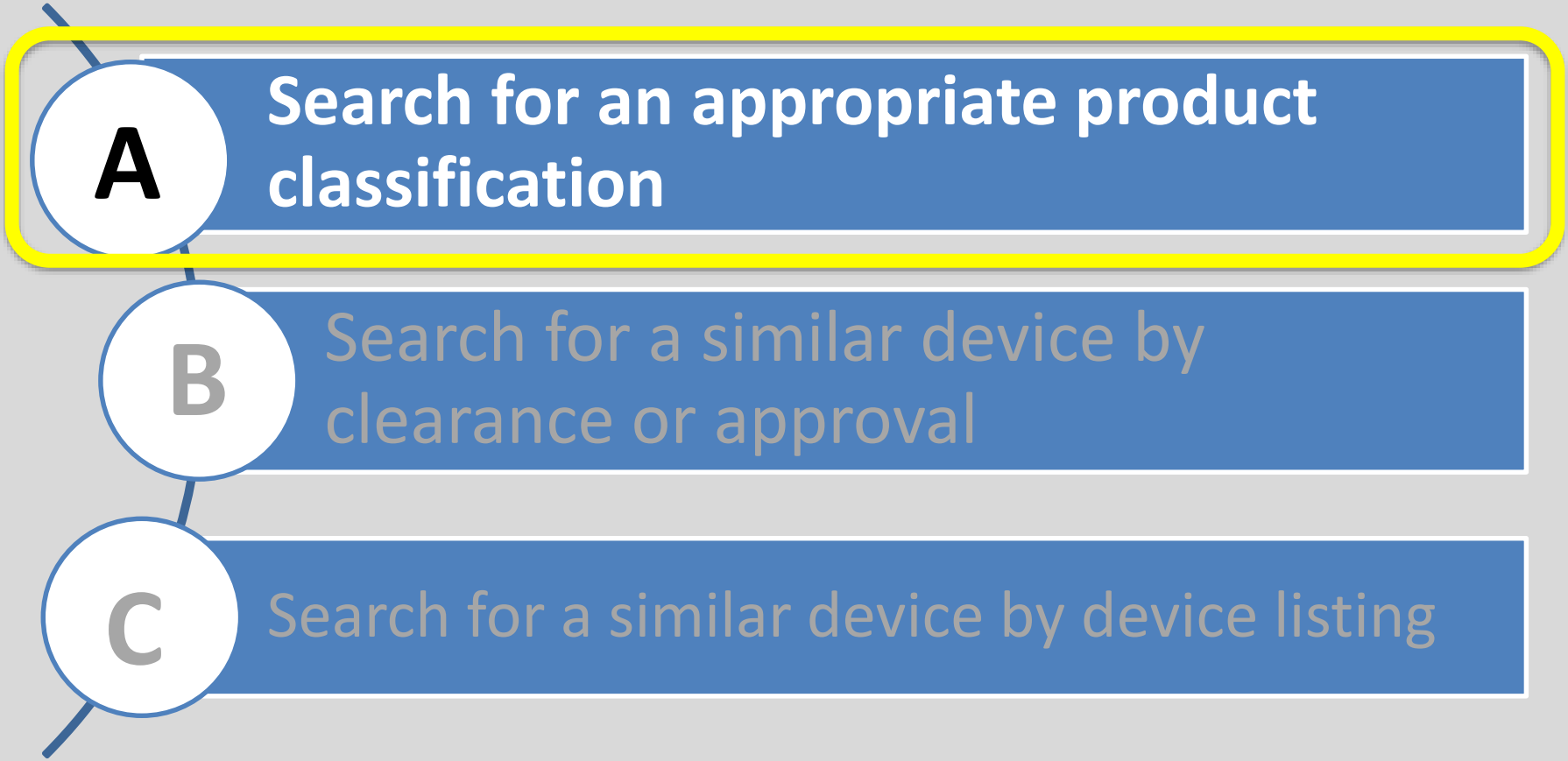
B

Search for a similar device by clearance or approval

C

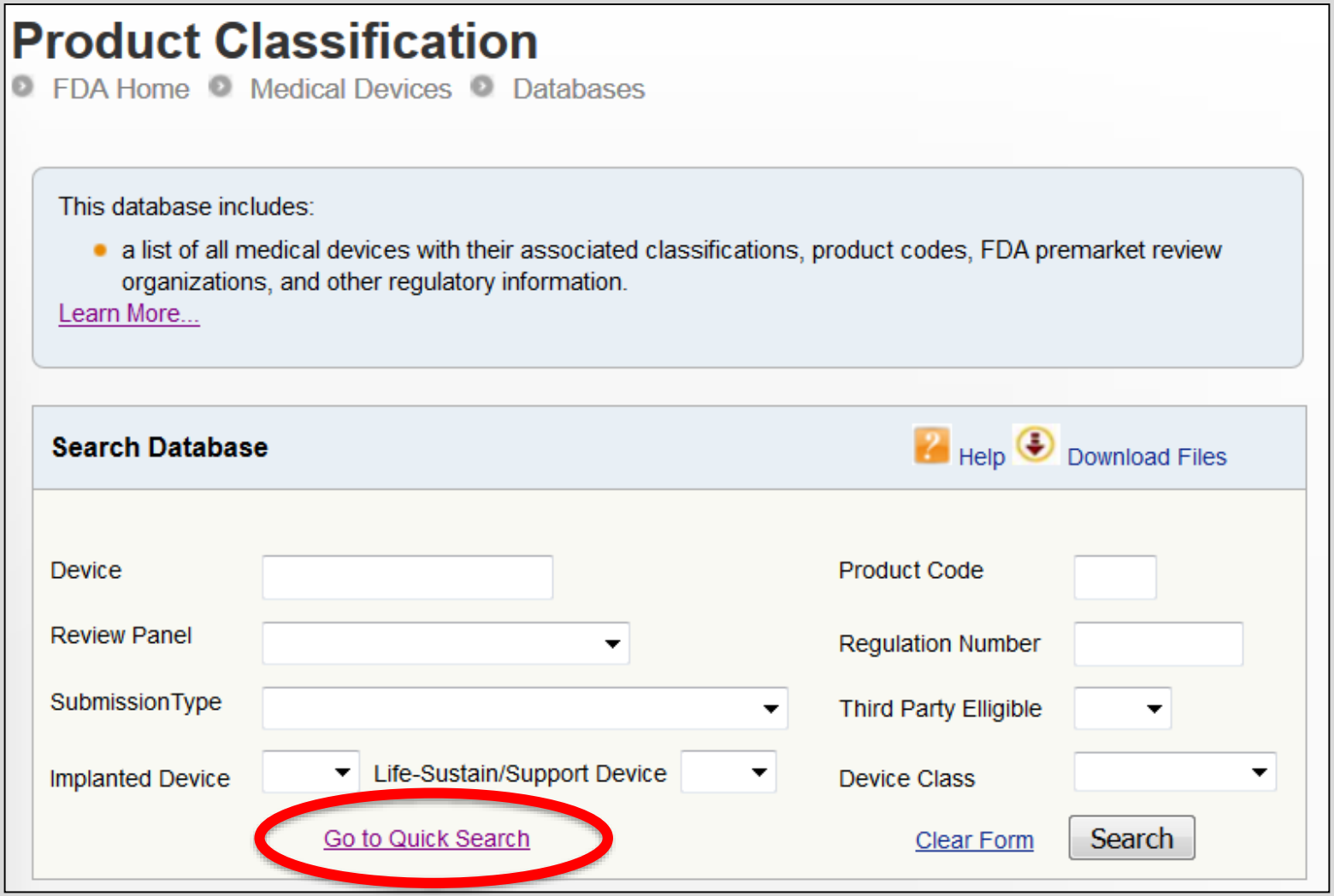
Search for a similar device by device listing

Classification Determination Methods

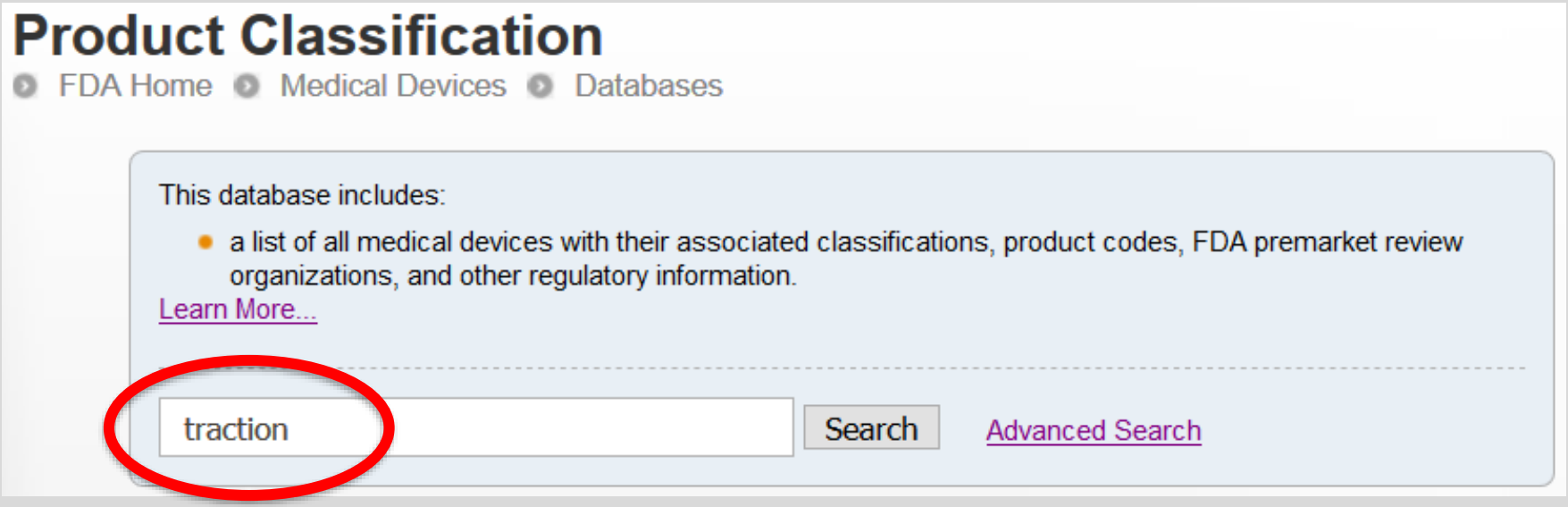


Method A:

Search Product Classification Database



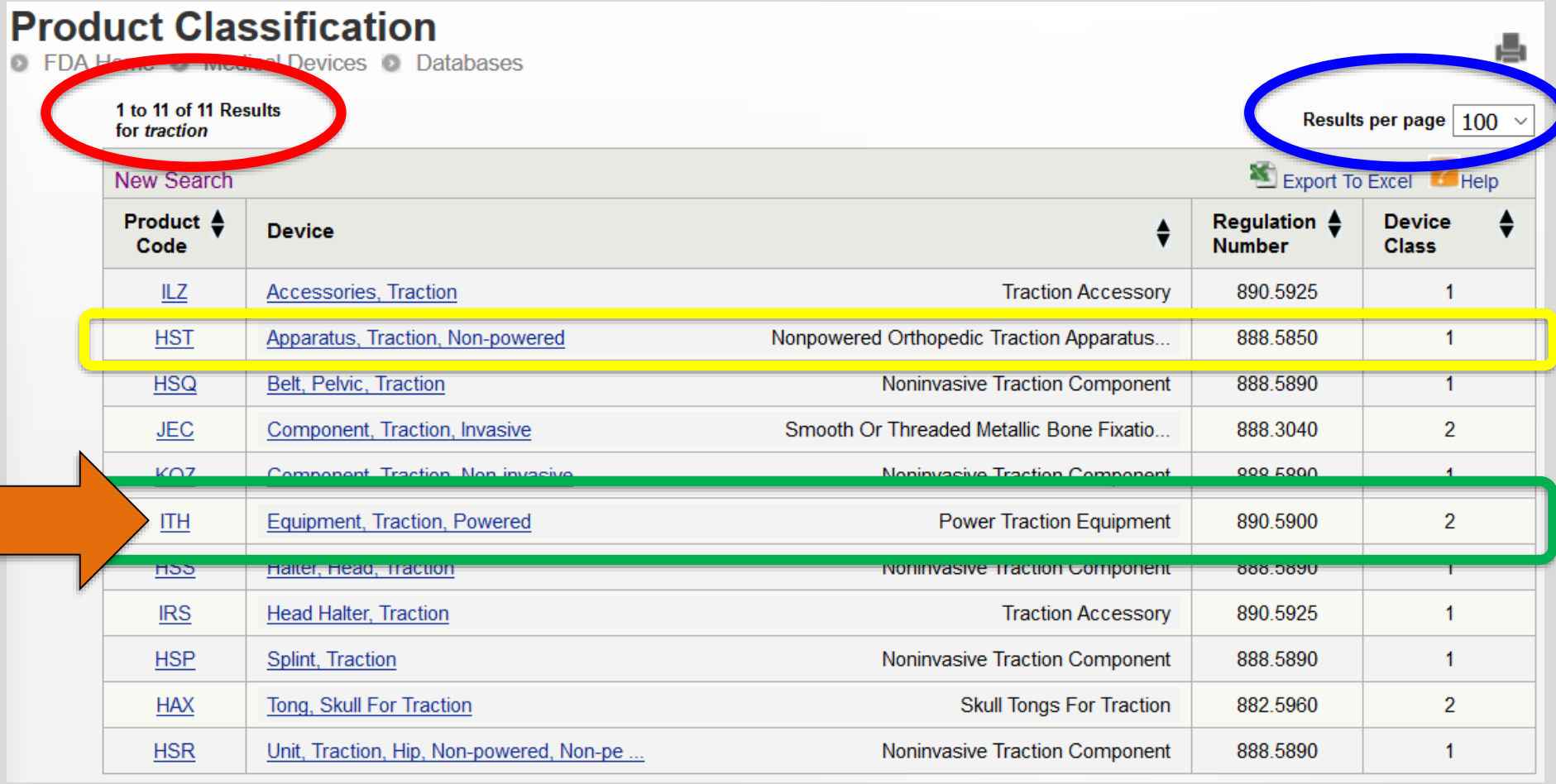
Method A: Search Product Classification



Search Reminders:

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

Method A: Search Product Classification



Product Classification

FDA Home › Medical Devices › Databases

1 to 11 of 11 Results for *traction*

Results per page 100

New Search | Export To Excel | Help

Product Code	Device		Regulation Number	Device Class
ILZ	Accessories, Traction	Traction Accessory	890.5925	1
HST	Apparatus, Traction, Non-powered	Nonpowered Orthopedic Traction Apparatus...	888.5850	1
HSQ	Belt, Pelvic, Traction	Noninvasive Traction Component	888.5890	1
JEC	Component, Traction, Invasive	Smooth Or Threaded Metallic Bone Fixatio...	888.3040	2
KOZ	Component, Traction, Non-invasive	Noninvasive Traction Component	888.5890	1
ITH	Equipment, Traction, Powered	Power Traction Equipment	890.5900	2
HSS	Halter, Head, Traction	Noninvasive Traction Component	888.5890	1
IRS	Head Halter, Traction	Traction Accessory	890.5925	1
HSP	Splint, Traction	Noninvasive Traction Component	888.5890	1
HAX	Tong, Skull For Traction	Skull Tongs For Traction	882.5960	2
HSR	Unit, Traction, Hip, Non-powered, Non-pe ...	Noninvasive Traction Component	888.5890	1

Method A: Search Product Classification

Device	Equipment, Traction, Powered
Regulation Description	Power traction equipment.
Regulation Medical Specialty	Physical Medicine
Review Panel	Physical Medicine
Product Code	ITH
Premarket Review	Neurological and Physical Medicine Devices (OHT5) Neuromodulation and Rehabilitation Devices (DHT5B)
Regulation Number	890.5900
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	No
Life-Sustain/Support Device?	No

Method A: Search Product Classification

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2018]
[CITE: 21CFR890.5900]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 890 -- PHYSICAL MEDICINE DEVICES

Subpart F--Physical Medicine Therapeutic Devices

Sec. 890.5900 Power traction equipment.

(a) *Identification.* Powered traction equipment consists of powered devices intended for medical purposes for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body.

(b) *Classification.* Class II (performance standards).

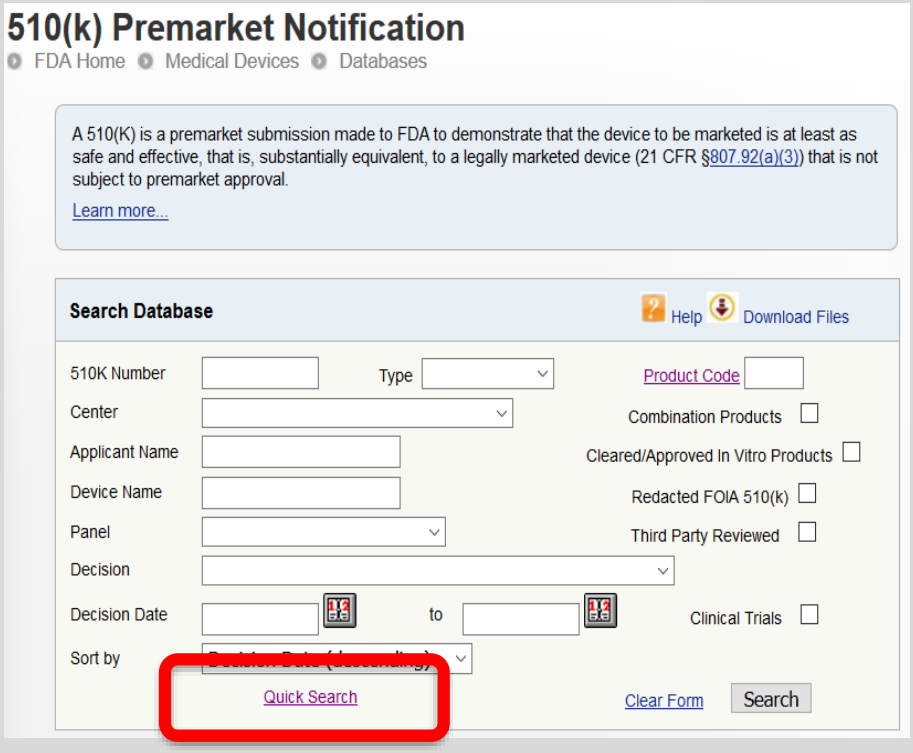
Classification Determination Methods

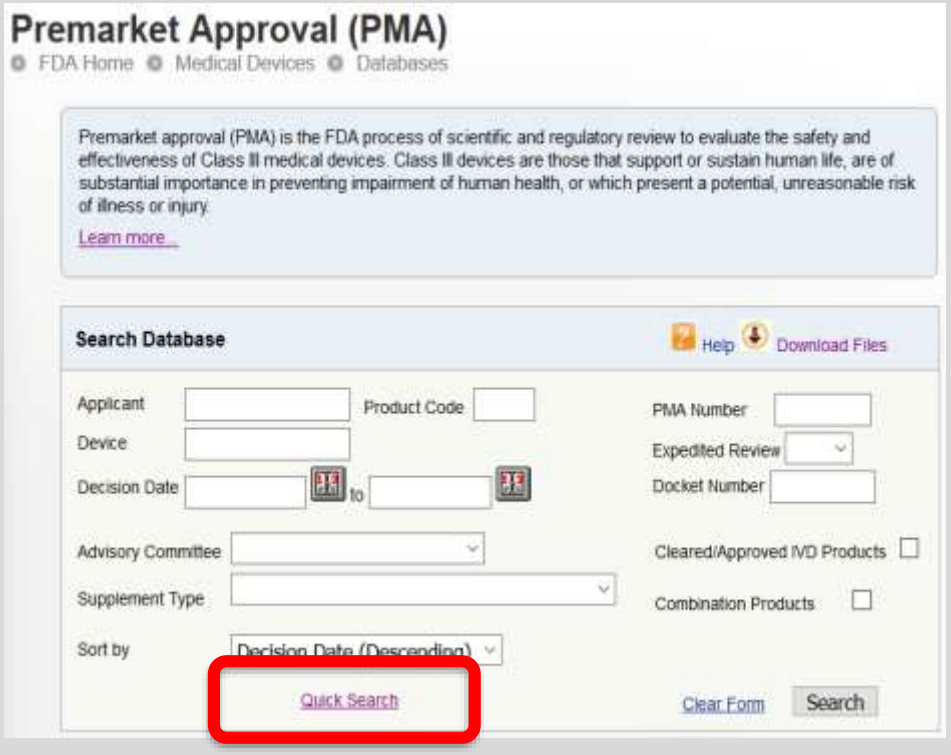
A. Search for an appropriate product classification

B. Search for a similar device by clearance or approval

C. Search for a similar device by device listing

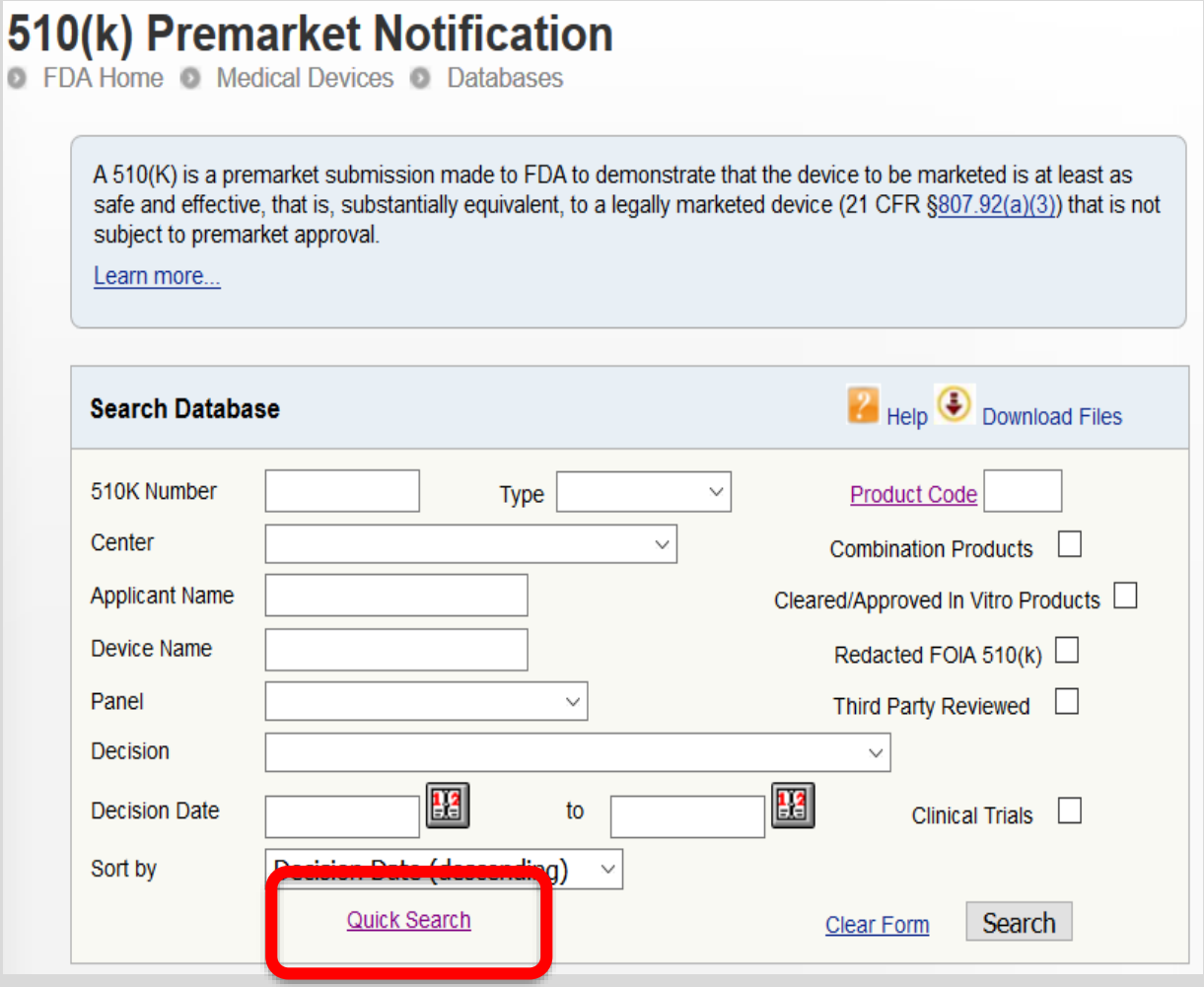
Method B:
Search 510(k) Clearance or PMA Database



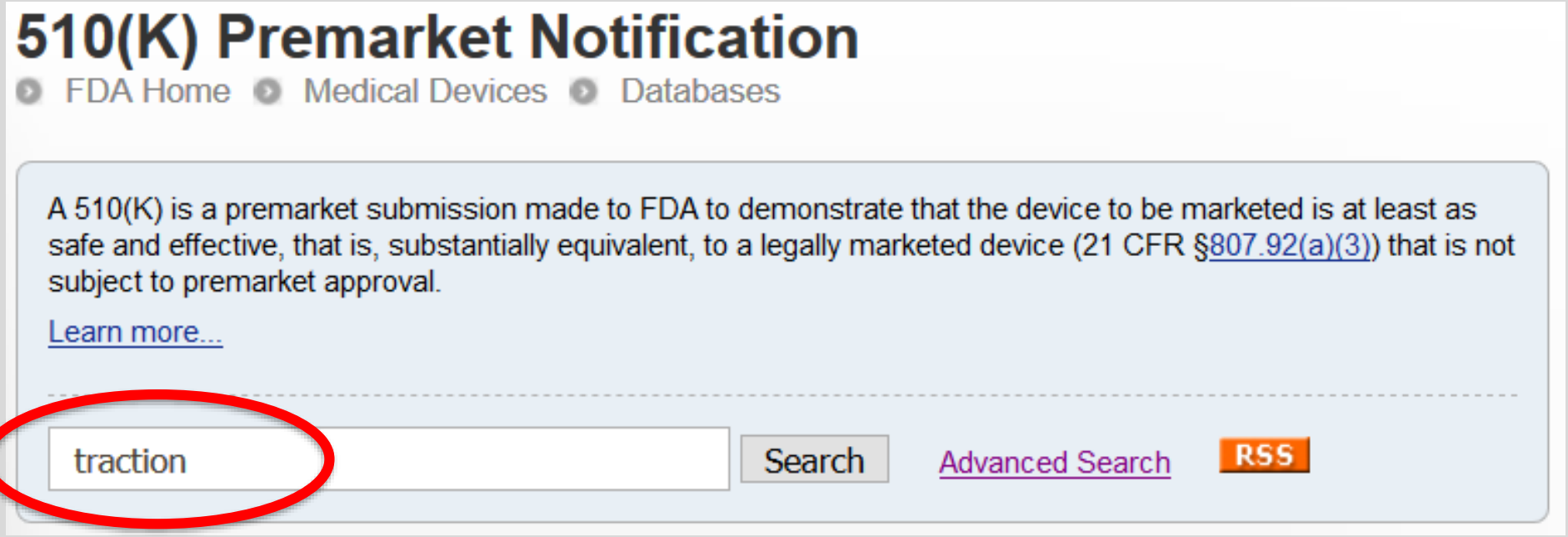


*De Novo Classification Requests Database

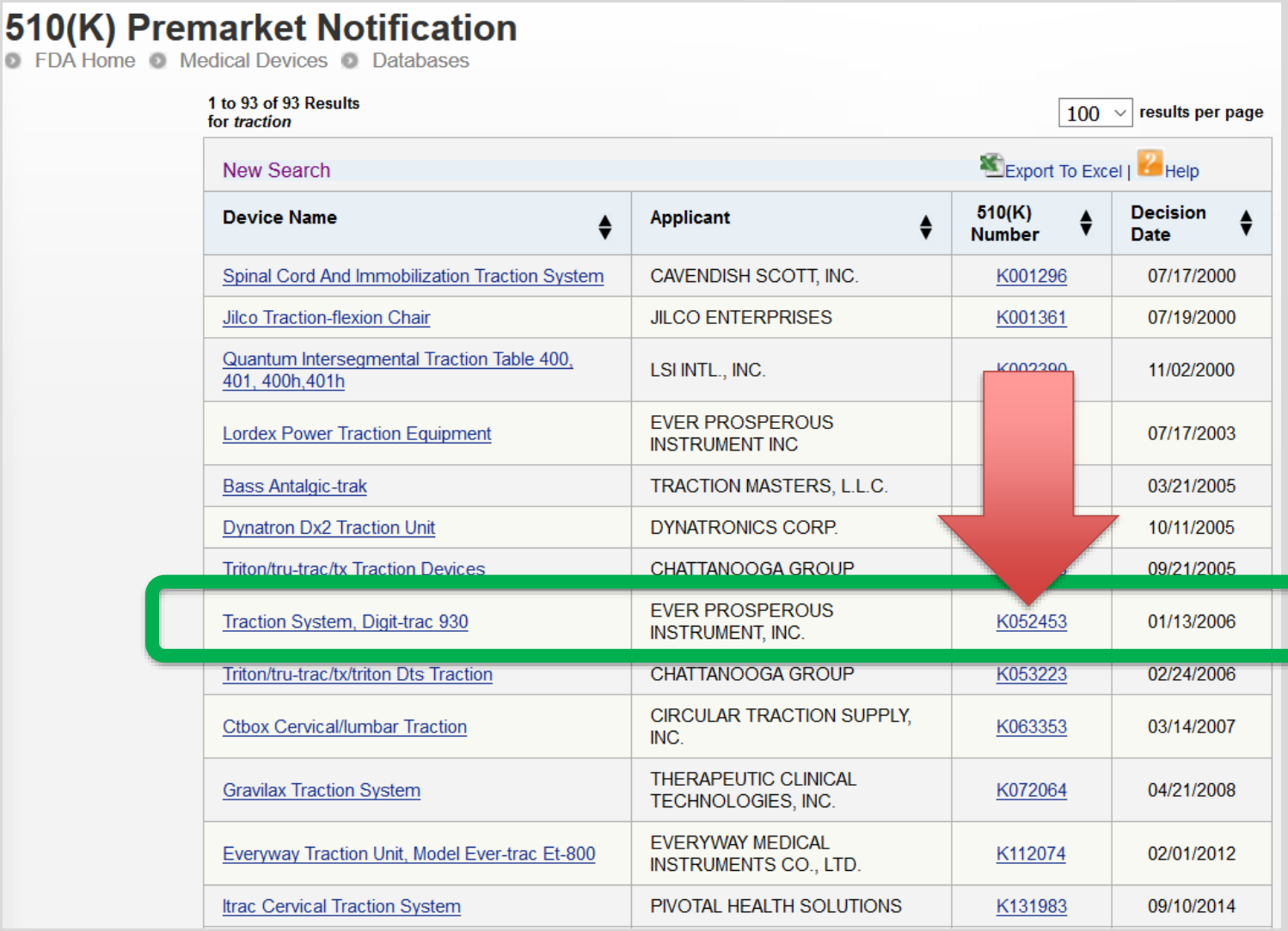
Method B:
Search 510(k) Clearance



Method B: Search 510(k) Clearance



Method B: Search 510(k) Clearance



510(K) Premarket Notification

FDA Home • Medical Devices • Databases

1 to 93 of 93 Results
for *traction*

100 results per page

New Search | Export To Excel | Help

Device Name	Applicant	510(K) Number	Decision Date
Spinal Cord And Immobilization Traction System	CAVENDISH SCOTT, INC.	K001296	07/17/2000
Jilco Traction-flexion Chair	JILCO ENTERPRISES	K001361	07/19/2000
Quantum Intersegmental Traction Table 400, 401, 400h,401h	LSI INTL., INC.	K002390	11/02/2000
Lordex Power Traction Equipment	EVER PROSPEROUS INSTRUMENT INC		07/17/2003
Bass Antalgic-trak	TRACTION MASTERS, L.L.C.		03/21/2005
Dynatron Dx2 Traction Unit	DYNATRONICS CORP.		10/11/2005
Triton/tru-trac/tx Traction Devices	CHATTANOOGA GROUP		09/21/2005
Traction System, Digit-trac 930	EVER PROSPEROUS INSTRUMENT, INC.	K052453	01/13/2006
Triton/tru-trac/tx/triton Dts Traction	CHATTANOOGA GROUP	K053223	02/24/2006
Ctbox Cervical/lumbar Traction	CIRCULAR TRACTION SUPPLY, INC.	K063353	03/14/2007
Gravilax Traction System	THERAPEUTIC CLINICAL TECHNOLOGIES, INC.	K072064	04/21/2008
Everyway Traction Unit, Model Ever-trac Et-800	EVERYWAY MEDICAL INSTRUMENTS CO., LTD.	K112074	02/01/2012
Itrac Cervical Traction System	PIVOTAL HEALTH SOLUTIONS	K131983	09/10/2014

Method B: Search 510(k) Clearance

Device Classification Name	Equipment, Traction, Powered
510(k) Number	K052453
Device Name	TRACTION SYSTEM, DIGIT-TRAC 930
Applicant	EVER PROSPEROUS INSTRUMENT, INC. NO. 58, FU-CHIUN STREET Hsin Chu City, TW 30067
Applicant Contact	Ke-men Jen
Correspondent	EVER PROSPEROUS INSTRUMENT, INC. NO. 58, FU-CHIUN STREET Hsin Chu City, TW 30067
Correspondent Contact	Ke-men Jen
Regulation Number	890.5900
Classification Product Code	ITH
Date Received	[illegible]
Decision Date	01/13/2006
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Physical Medicine
510k Review Panel	Physical Medicine
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Classification Determination Methods

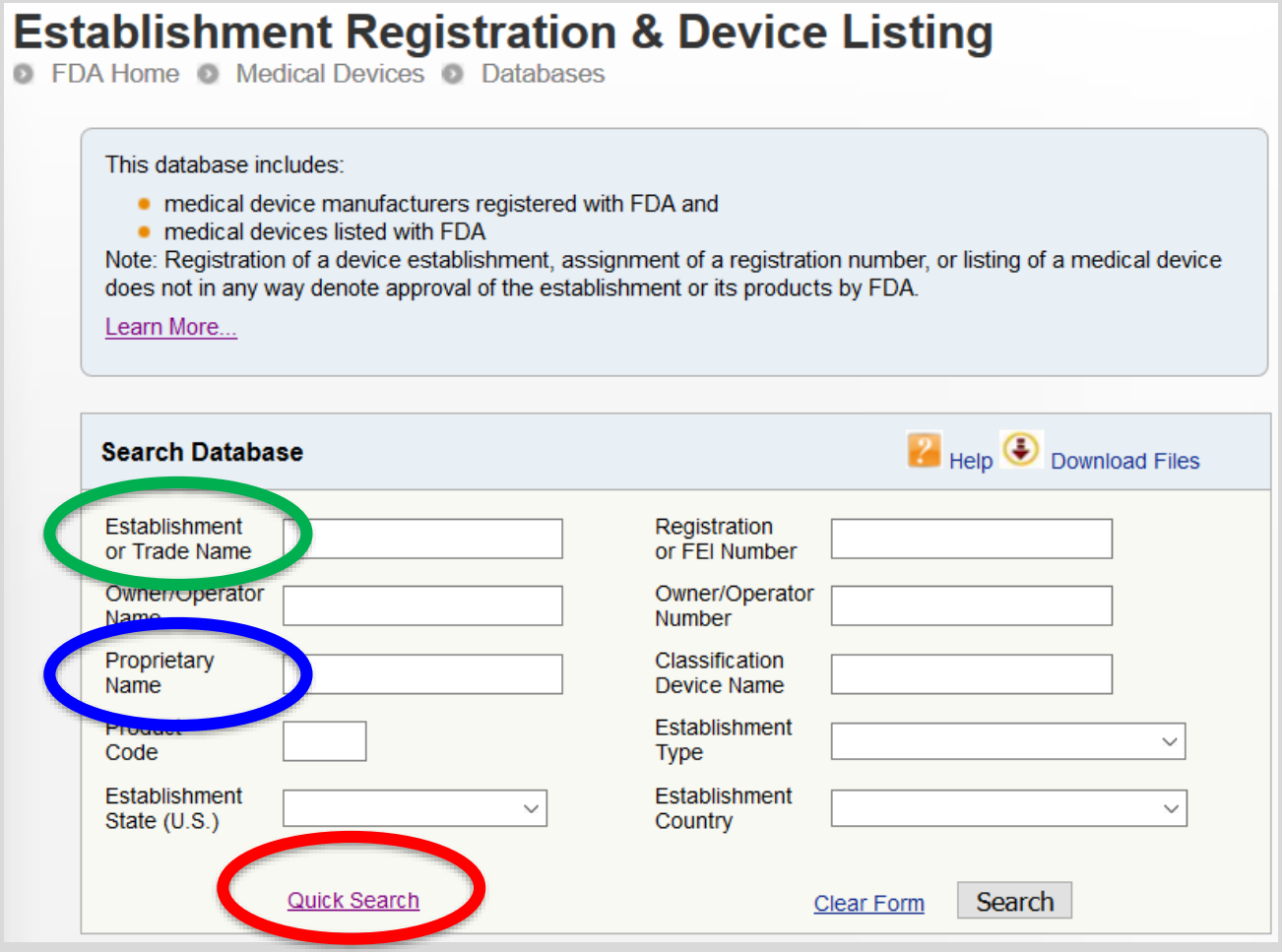
A. Search for an appropriate product classification

B. Search for a similar device by clearance or approval

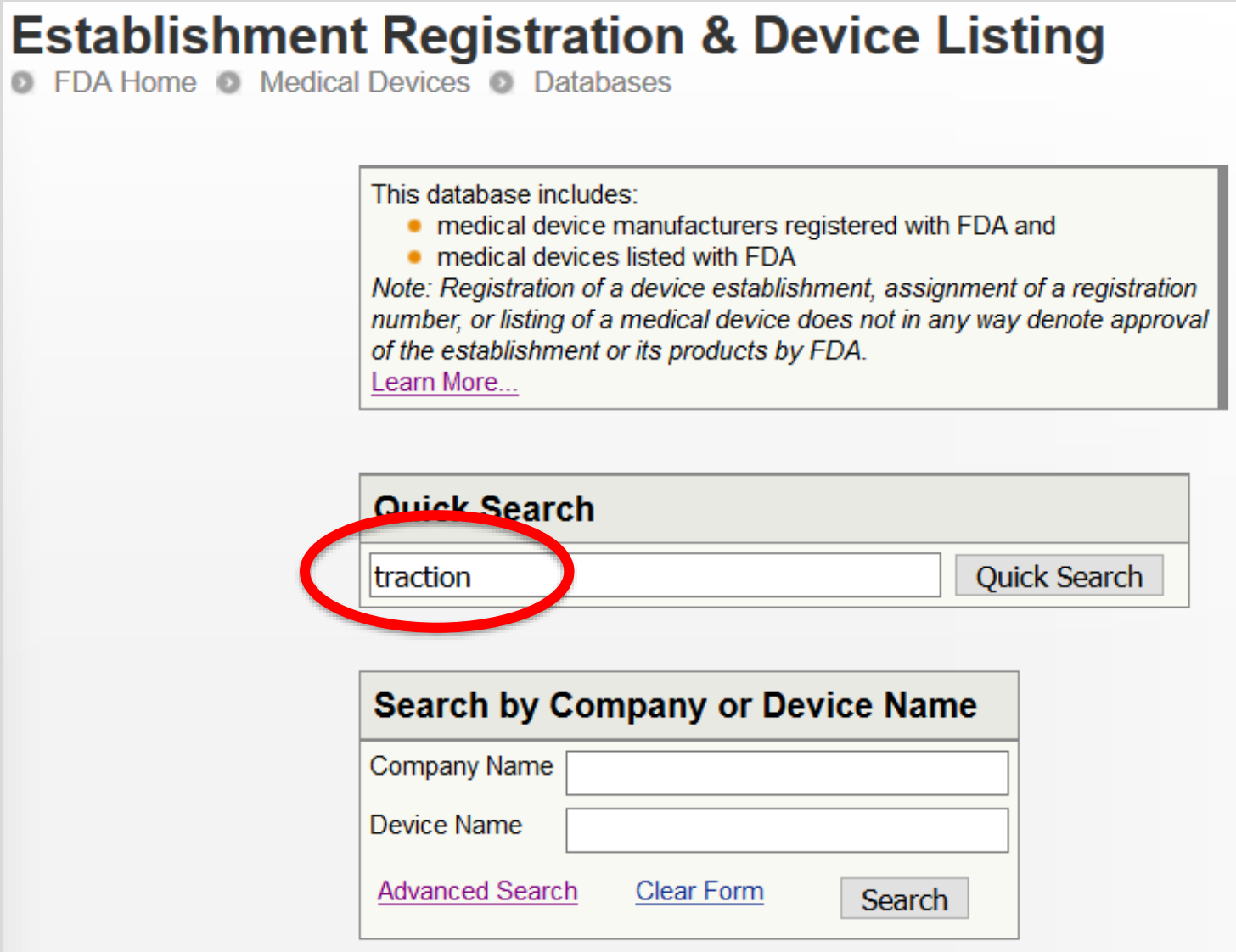
C. Search for a similar device by device listing

Method C:

Search Establishment Registration and Device Listing Database



Method C: Search Device Listing



Method C: Search Device Listing

Establishment Registration & Device Listing

FDA Home ▸ Medical Devices ▸ Databases

1 to 10 of 22 Results found
for *traction*

1 2 3 >

Results per Page 10
New Search

Establishment Name		Product
BACK BUBBLE	SOLANA BEACH , CA	Chase Lumbar Traction Device Apparatus, Traction, Non-Powered • [show all products for *BACK BUBBLE* SOLANA BEACH , CA]
CARPAL DOCTORS LLC	Wellington , FL	Ctrac Apparatus, Traction, Non-Powered • [show all products for *CARPAL DOCTORS LLC* Wellington , FL]
CHI-BO INDUSTRY CO., LTD.	HOU LI HSIANG, TAICHUNG HSIEN Taichung - TW	EP; FitForm; FitSpine; INVERSION TABLE; Invertalign; NXT-R; Teeter Hang Ups Apparatus, Traction, Non-Powered • [show all products for *CHI-BO INDUSTRY CO., ...* HOU LI HSIANG, TAICHUNG HSIEN Taichung - TW]
CIRCULAR TRACTION SUPPLY, INC.	HUNTINGTON BEACH , CA	• [show all products for *CIRCULAR TRACTION SU ...* HUNTINGTON BEACH , CA]
CORFLEX	MANCHESTER , NH	NONINVASIVE TRACTION COMPONENT Component, Traction, Non-Invasive • [show all products for *CORFLEX* MANCHESTER , NH]
DJO, LLC	VISTA , CA	Saunders Pelvic Traction Belt Belt, Pelvic, Traction
EVER PROSPEROUS INSTRUMENT, INC.	New Taipei City Taipei - District TW	TRACTION SYSTEM, DIGIT-TRAC 930 Equipment, Traction, Powered • [show all products for *EVER PROSPEROUS INST ...* New Taipei City Taipei - District TW]
EVER PROSPEROUS INSTRUMENT, INC.	New Taipei City Taipei - District TW	EVER PROSPEROUS Equipment, Traction, Powered • [show all products for *EVER PROSPEROUS INST ...* New Taipei City Taipei - District TW]

Method C: Search Device Listing

Proprietary Name:	TRACTION SYSTEM, DIGIT-TRAC 930
Classification Name:	EQUIPMENT, TRACTION, POWERED
Product Code:	ITH
Device Class:	2
Regulation Number:	890.5900
Medical Specialty:	Physical Medicine
Registered Establishment Name:	EVER PROSPEROUS INSTRUMENT, INC.
Registered Establishment Number:	1000635107
Premarket Submission Number:	K052453
Owner/Operator:	EVER PROSPEROUS INSTRUMENT, INC.
Owner/Operator Number:	9075179
Establishment Operations:	Manufacturer

Case Study Summary

Question	Conclusion
Does my powered traction device meet the definition of a medical device?	Yes
How would it be classified?	Class II, Product Code ITH
What regulatory requirements apply to my medical device?	General Controls and Requires 510(k) Clearance

Presentation Summary

- A clearly defined intended use is key
- Medical devices are classified based on risk
- The risk of the device determines the extent of regulatory controls
- The class and regulatory requirements for a medical device may be determined by searching FDA's public databases

Questions

Your Call to Action

- Clearly define the intended use of your device
- Utilize and become familiar with FDA's public databases
- Consider different research methods to help you determine applicable regulatory requirements for your device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