Case Study:
How is My Medical Device Classified?

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Consumer Safety Officer
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

How to Use this Presentation

1. How is My Medical Device Classified?
2. **Case Study: How is My Medical Device Classified?**

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**

Learning Objective

Describe how to approach classifying a product using three different classification determination methods:

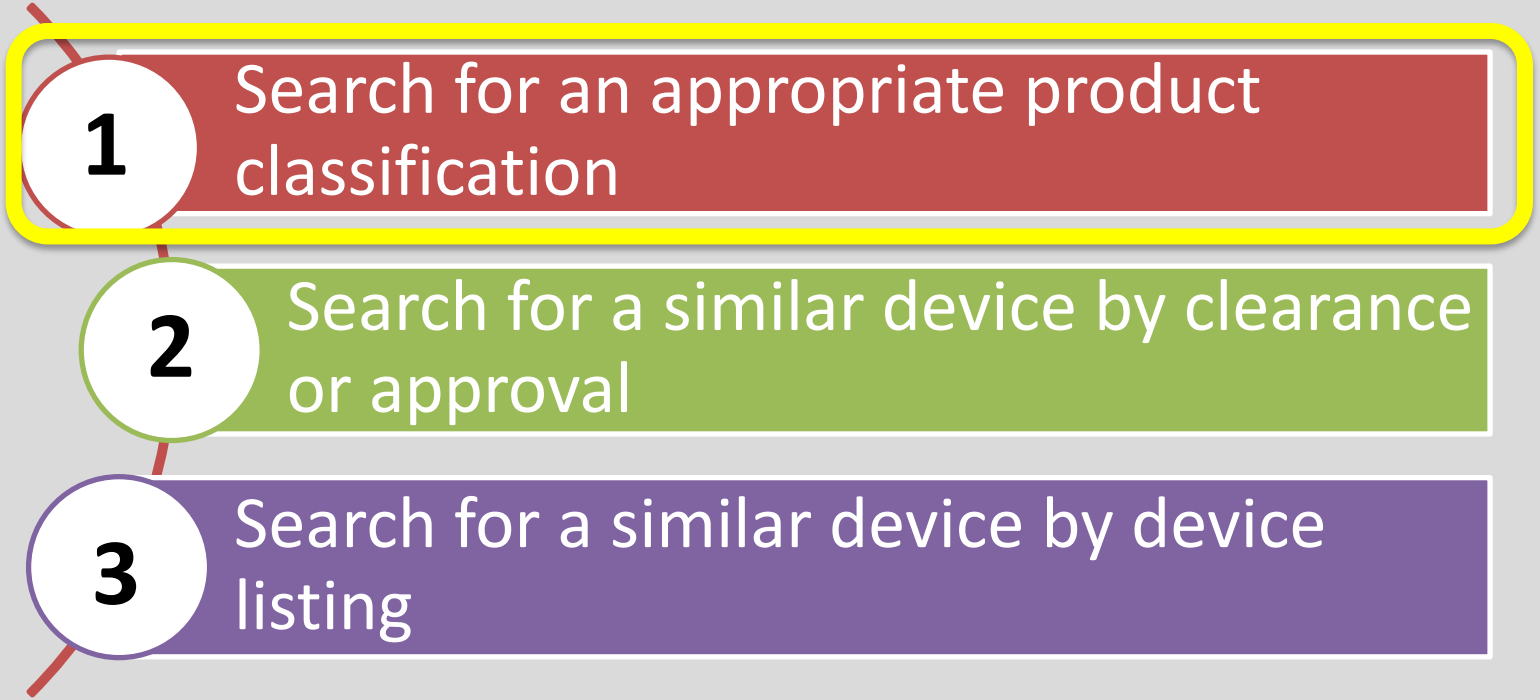
1. Search for an appropriate product classification
2. Search for a similar device by clearance or approval
3. Search for a similar device by device listing

Traction Device

Intended Use: To treat low back pain through intermittent and static traction

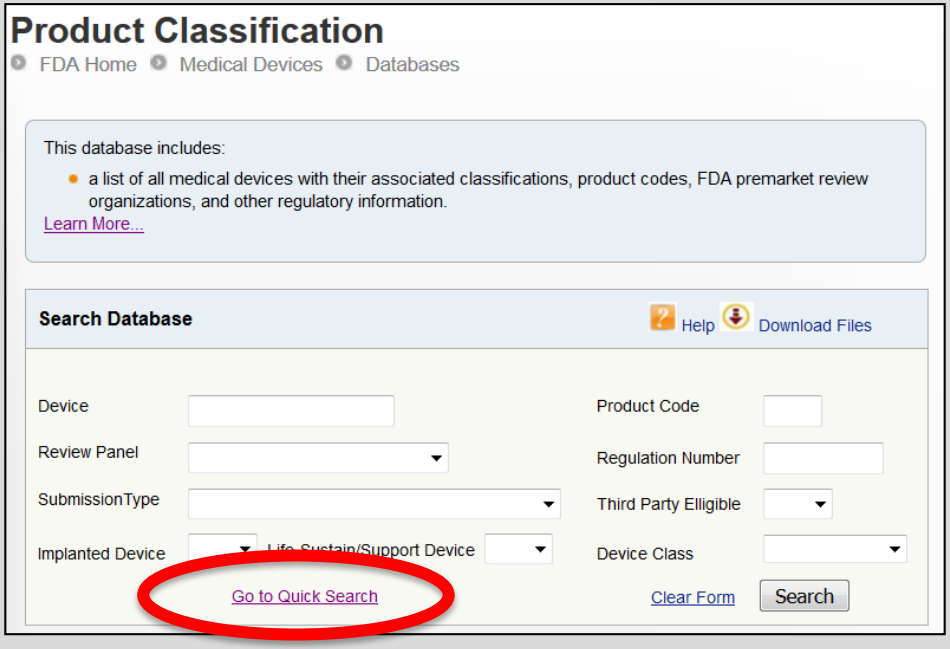
Classification Determination Methods

Classification Determination Methods

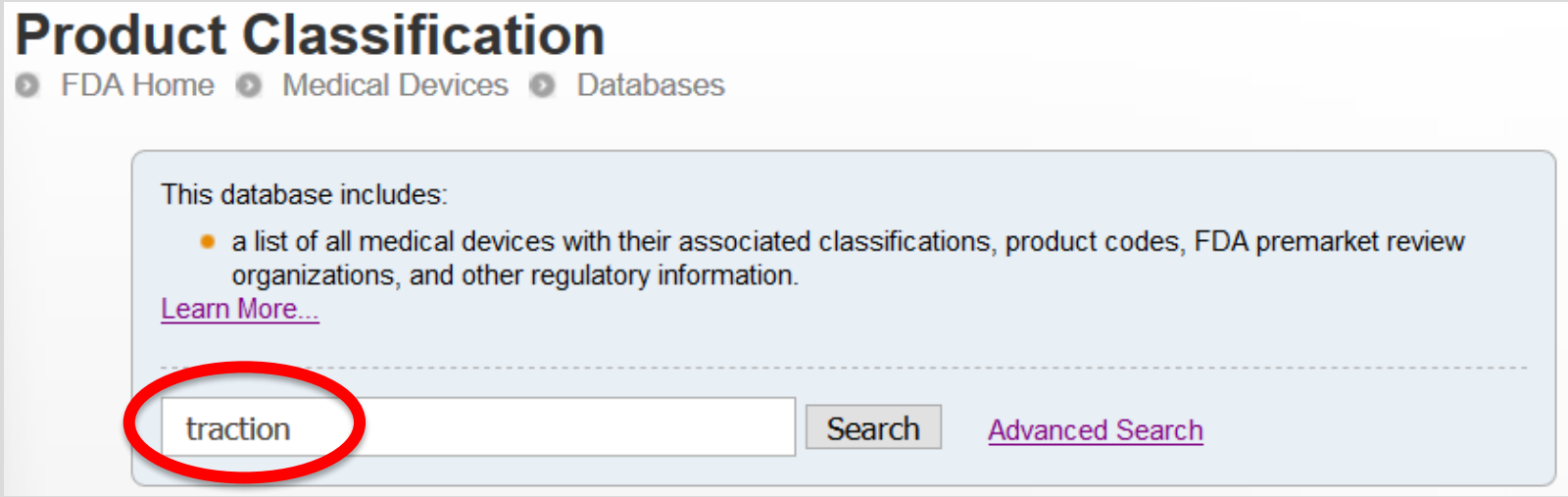


Method 1:
Search Product Classification Database

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm



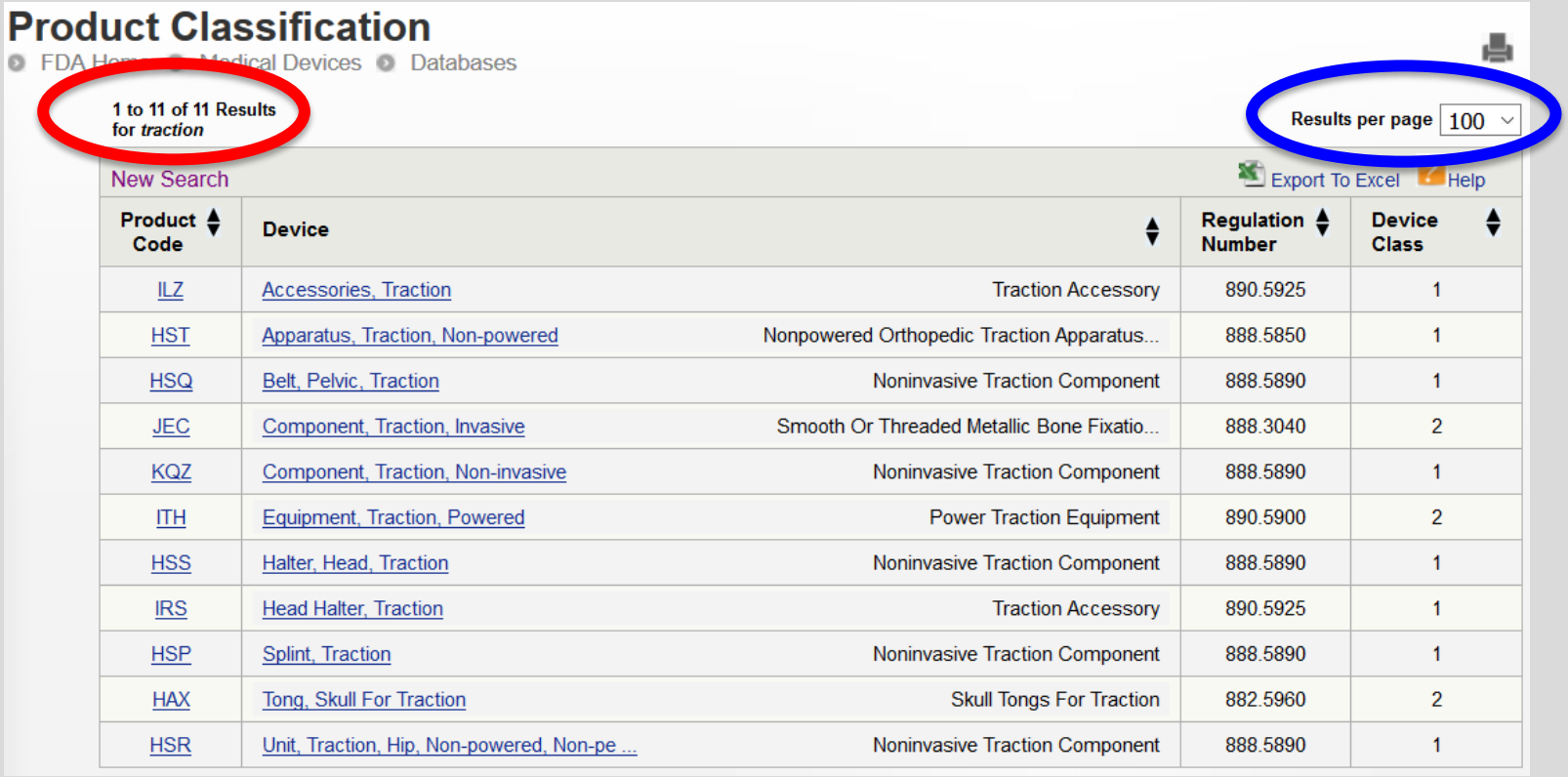
Method 1: Search Product Classification



Search Reminders:

- Conduct multiple searches using a variety of related terms
- Ensure correct spelling
- Avoid plurals

Method 1: Search Product Classification



Product Classification

FDA Home > Medical Devices > Databases

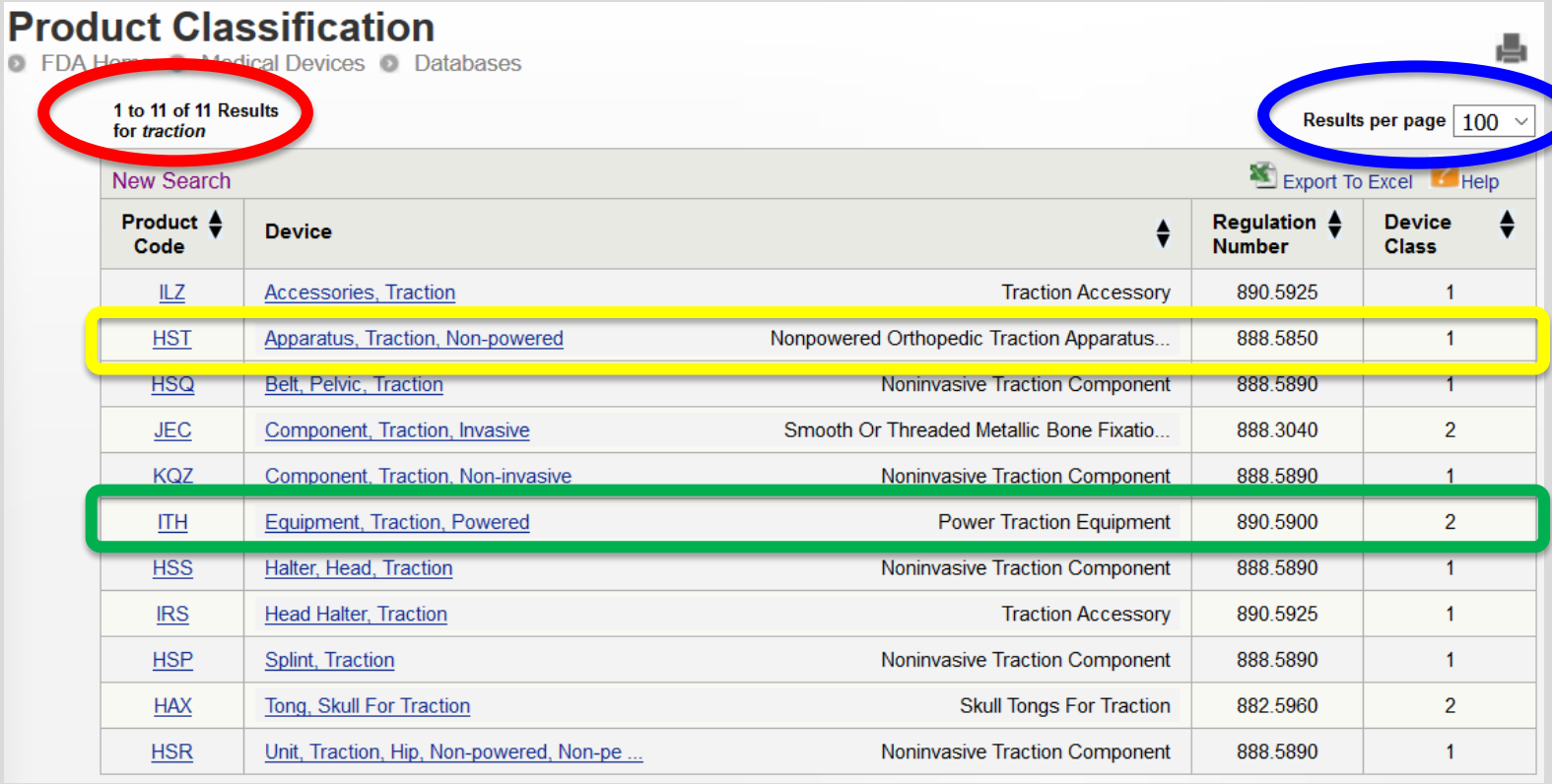
1 to 11 of 11 Results for *traction*

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
KQZ	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 1: Search Product Classification



Product Classification

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JEC	Component, Traction, Invasive	Smooth Or Threaded Metallic Bone Fixatio...	888.3040	2
KQZ	Component, Traction, Non-invasive	Noninvasive Traction Component	888.5890	1
ITH	Equipment, Traction, Powered	Power Traction Equipment	890.5900	2
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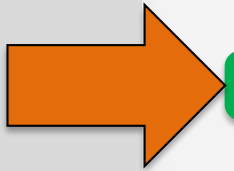

Product Classification

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Method 1: 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)
Submission Type	510(k)
Regulation Number	890.5900
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	No
Life-Sustain/Support Device?	No

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Method 1: Search Product Classification

PART 890 -- PHYSICAL MEDICINE DEVICES

Subpart F--Physical Medicine Therapeutic Devices

Sec. 890.5900 Power traction equipment.

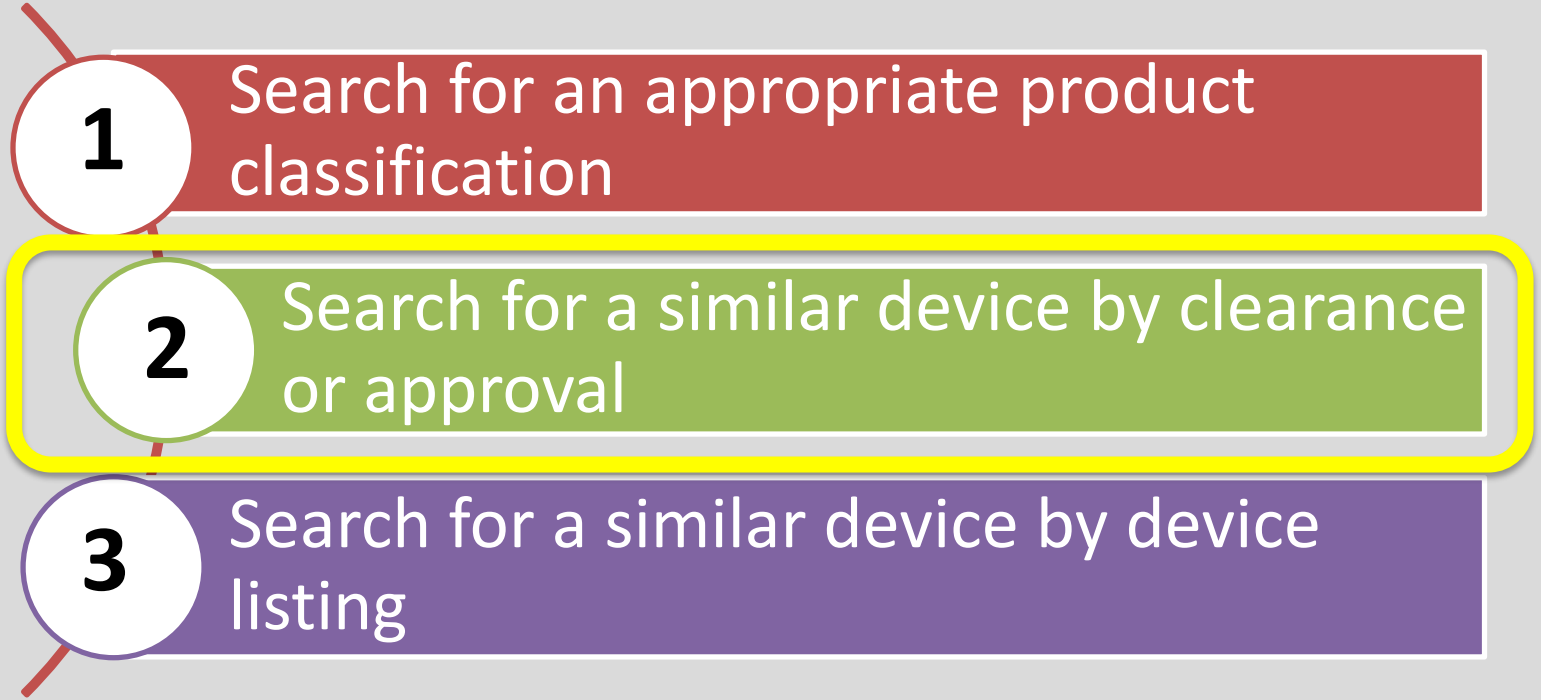
(a) *Identification.* Powered traction equipment consists of powered devices intended for medical purposes for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body.

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

Method 1: 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)
Submission Type	510(k)
Regulation Number	890.5850
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	No
Life-Sustain/Support Device?	No

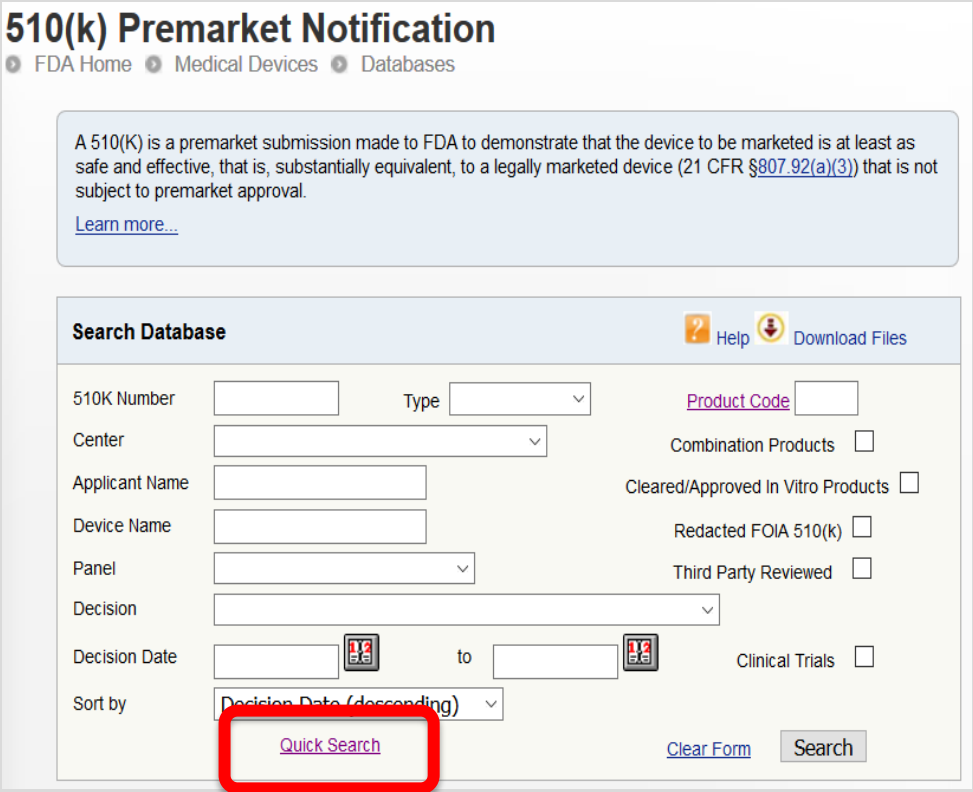
Classification Determination Methods



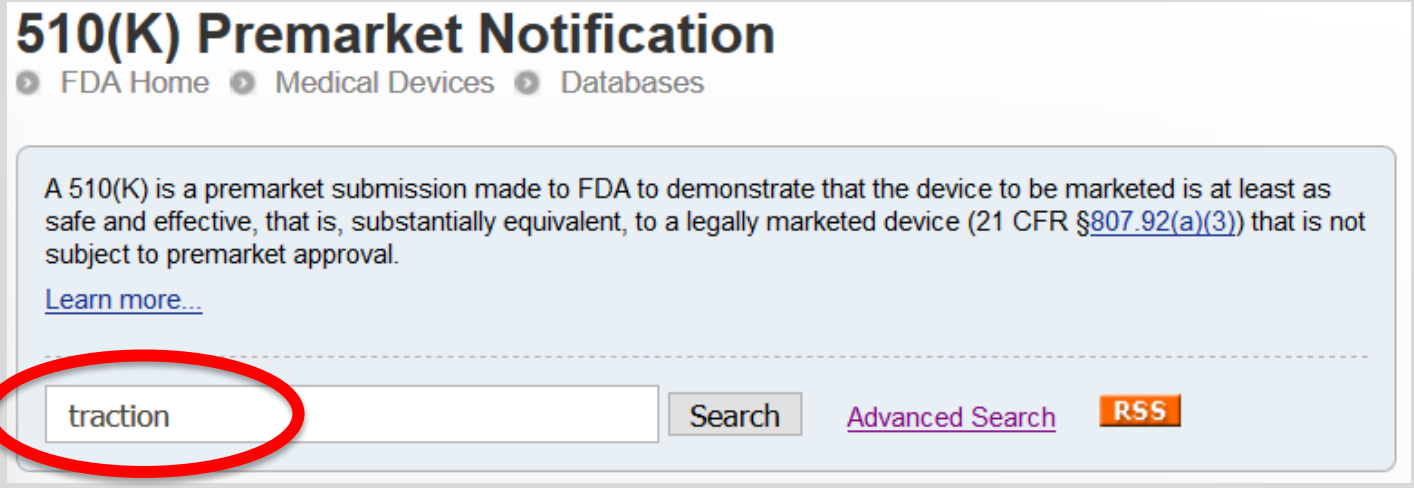
Method 2: Search for a Similar Device

- 510(k) Clearance
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- PMA Approval
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
- De Novo Database
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm

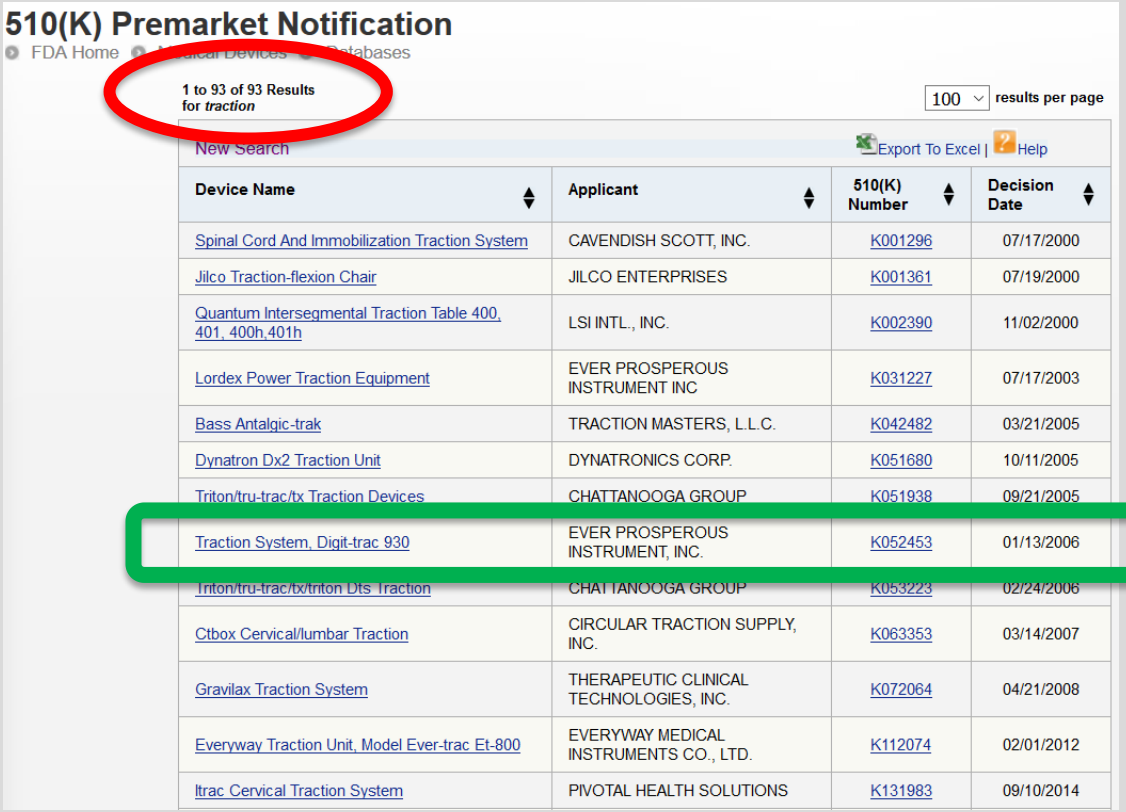
Method 2: Search by 510(k) Clearance



Method 2: Search 510(k) Clearance



Method 2: Search 510(k) Clearance



510(K) Premarket Notification

FDA Home

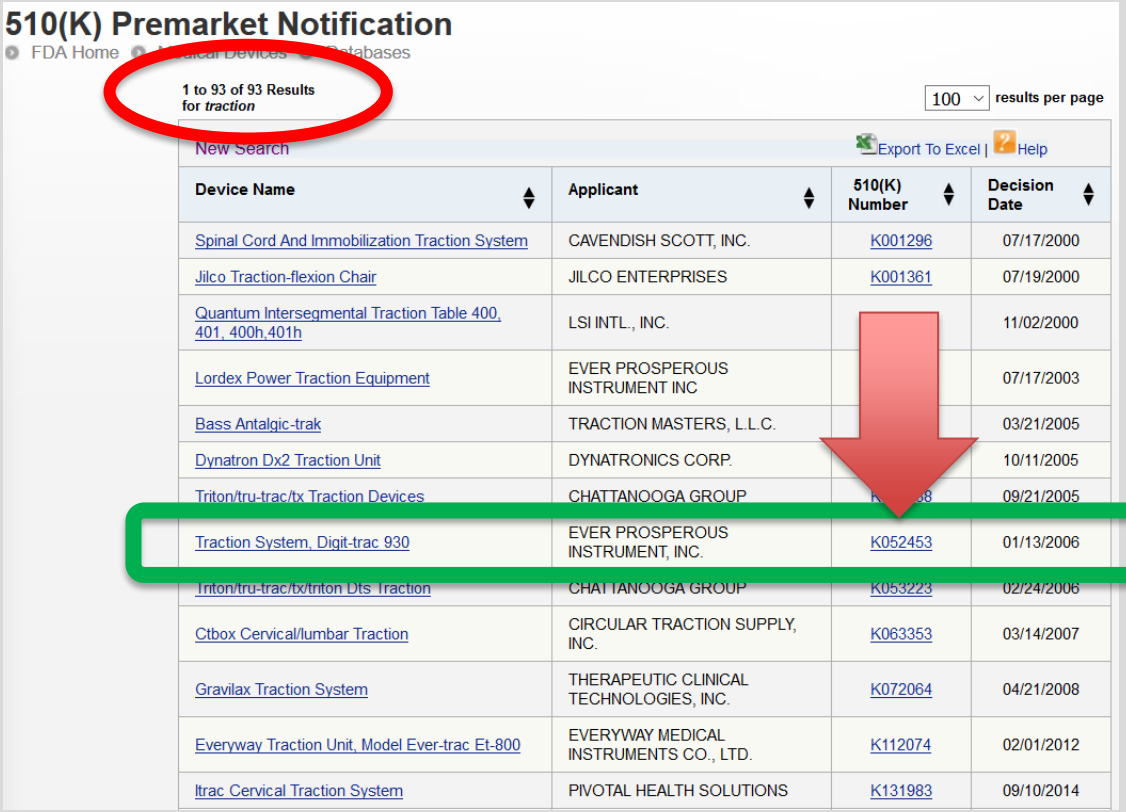
1 to 93 of 93 Results
for *traction*

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	K031227	07/17/2003
Bass Antalgic-trak	TRACTION MASTERS, L.L.C.	K042482	03/21/2005
Dynatron Dx2 Traction Unit	DYNATRONICS CORP.	K051680	10/11/2005
Triton/tru-trac/tx Traction Devices	CHATTANOOGA GROUP	K051938	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 2: Search 510(k) Clearance



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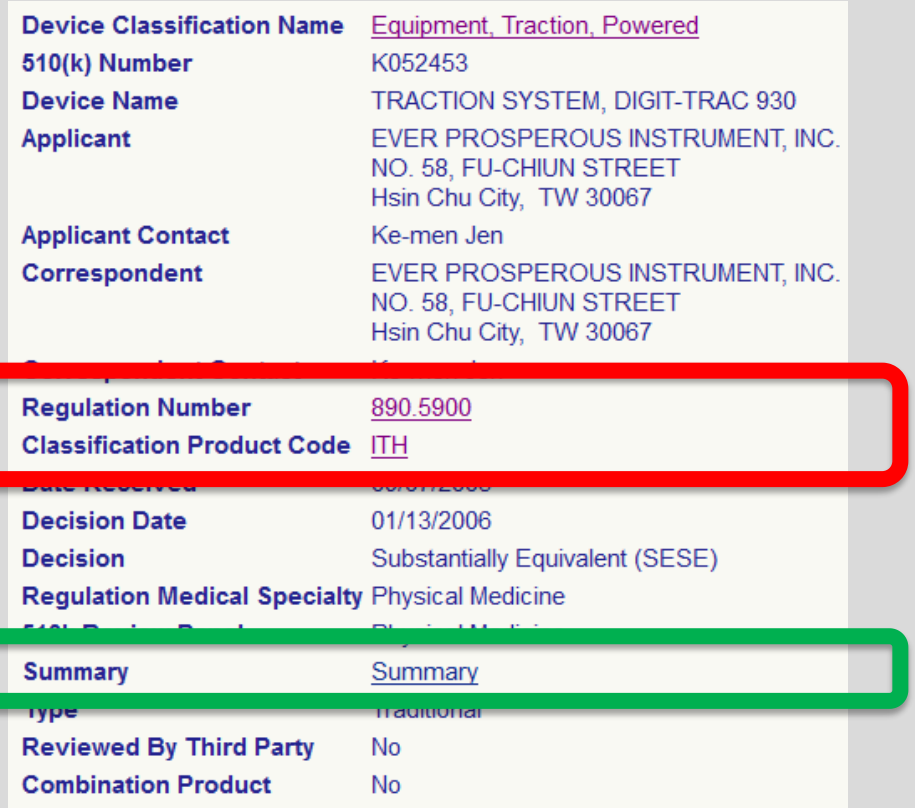
Traction System, Digit-trac 930	EVER PROSPEROUS INSTRUMENT, INC.	K052453	01/13/2006
Triton/tru-trac/tx/triton Dts Traction	CHATTANOOGA GROUP	K053223	02/24/2006
Ctbox Cervical/lumbar Traction	CIRCULAR TRACTION SUPPLY, INC.	K063353	03/14/2007
Gravilax Traction System	THERAPEUTIC CLINICAL TECHNOLOGIES, 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 2: 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
Regulation Number	890.5900
Classification Product Code	ITH
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

Method 2: Search 510(k) Clearance



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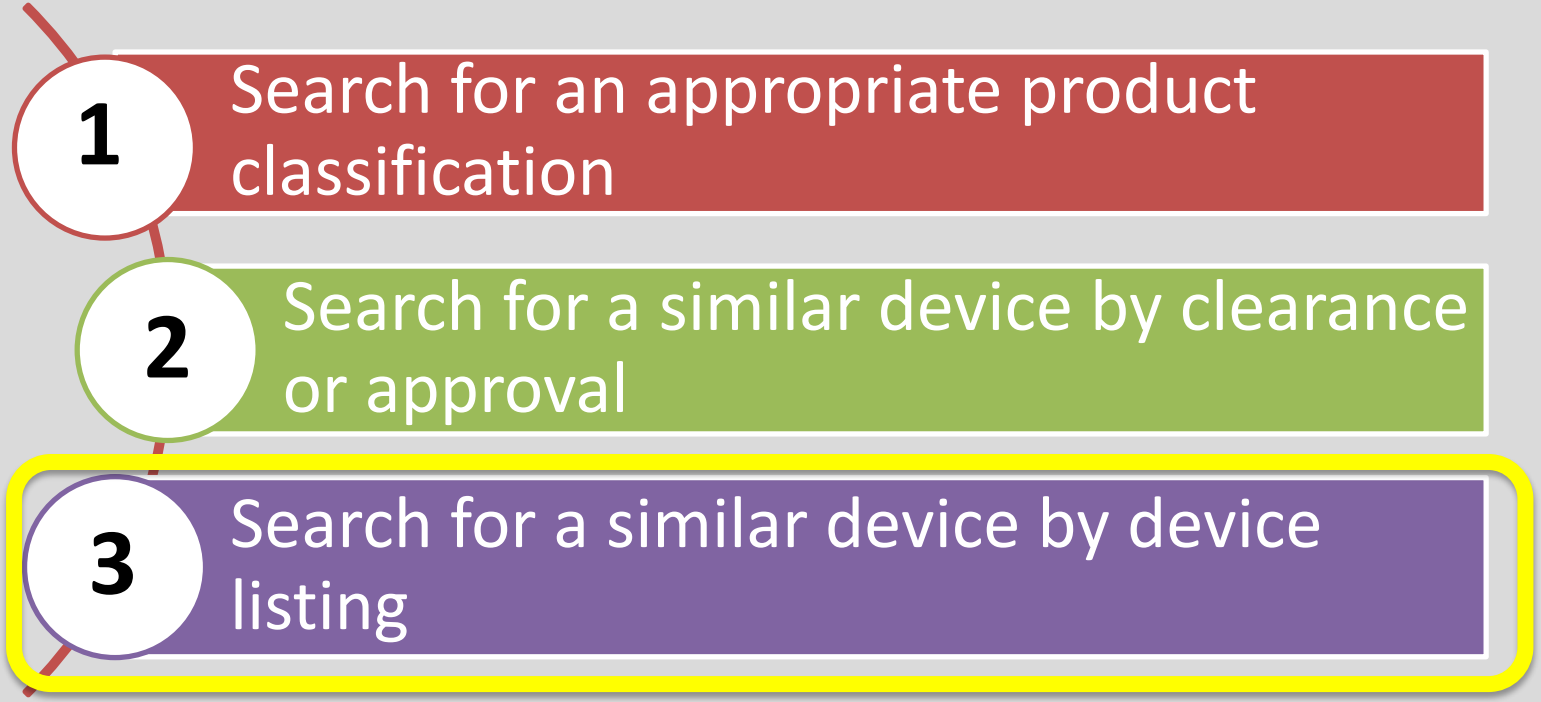
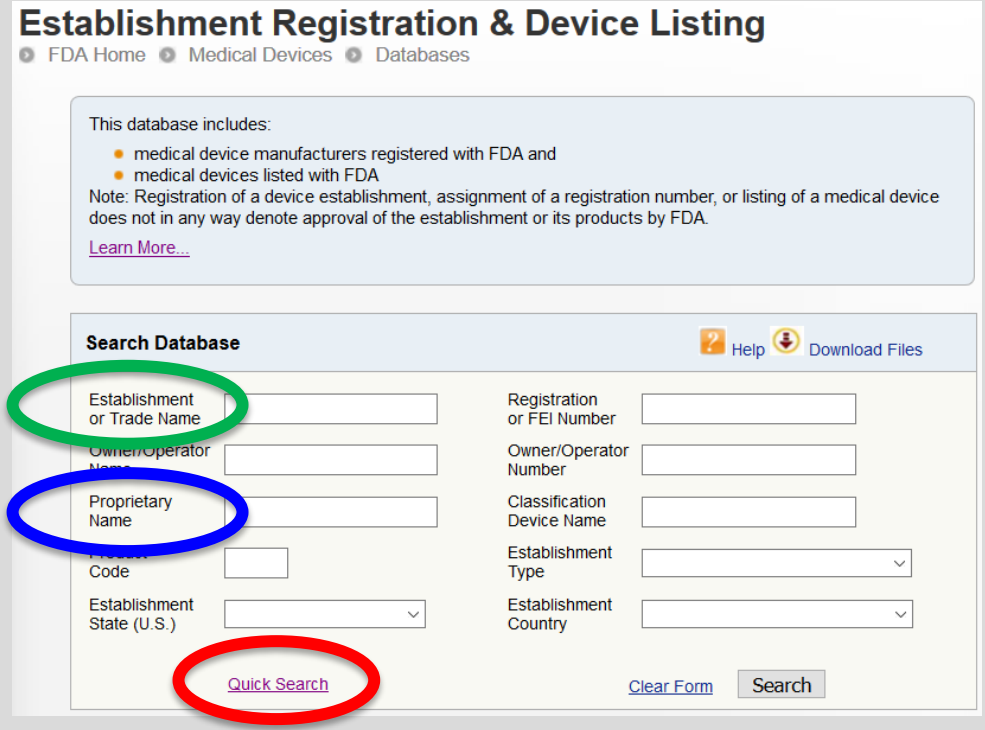
Classification Determination Methods



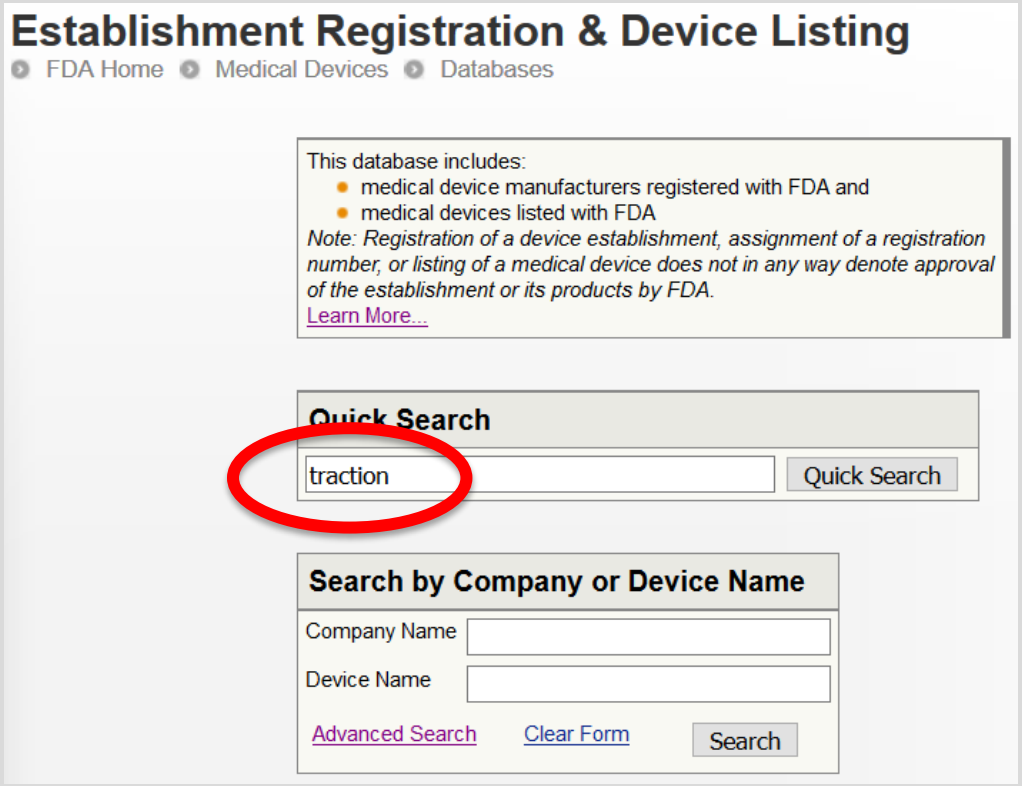
Method 3:

Search Establishment Registration and Device Listing Database

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm



Method 3: Search Device Listing



Method 3: 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 3: Search Device Listing

Establishment Registration & Device Listing

FDA Home › Medical Devices › Databases

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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 ... for *CIRCULAR TRACTION SU ...* HUNTINGTON BEACH , CA]
CORFLEX	MANCHESTER , NH	NONINVASIVE ... COMPONENT Component, Traction, Non-Invasive [show ... for *CORFLEX* MANCHESTER , NH]
DJO, LLC	VISTA , CA	Saunders ... it 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 3: 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

Product Classification Example

Powered Traction Device	
Class	II
Regulatory Controls	General **No special controls identified.*
Regulation	21 CFR 890.5900
Product Code	ITH
Premarket Submission	510(k)

Summary

- There are **three classification determination methods** available to you.

- Utilizing these methods will help you determine **how your medical device may be classified**.

Resources

Slide Number	Cited Resource	URL
8	Product Classification Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm
18	510(k) Clearance Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
18	Premarket Approval (PMA) Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
18	De Novo Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm
26	Establishment Registration and Device Listing	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Providing Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - over 100 modules - videos, audio recordings, PowerPoint presentations, software-based “how to” modules
   - accessible on your portable devices: **www.fda.gov/CDRHLearn**

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics: **www.fda.gov/DeviceAdvice**

3. **Division of Industry and Consumer Education (DICE)**
   - Email: DICE@fda.hhs.gov
   - Phone: 1-800-638-2041 or (301) 796-7100 (Live Agents 9 am – 12:30 pm; 1 – 4:30 pm ET)

Your Call to Action

- Conduct **multiple searches** in each of the databases
- **Cross-check** yourself by utilizing all three classification determination methods


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ADMINISTRATION