UDI Implementation

US Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)

July 7, 2015

Objectives of the UDI Program

Establish a system to adequately identify devices through distribution and use

- Facilitate the rapid and accurate identification of a device
- Enable access to important information concerning the device
- Provide a standard and clear way to document device use in electronic health records, clinical information systems, and registries

Key Benefits of UDI

Improve Patient Safety

More Accurate Understanding of Device Benefit-Risk Profile

Facilitate Device Innovation and Patient Access

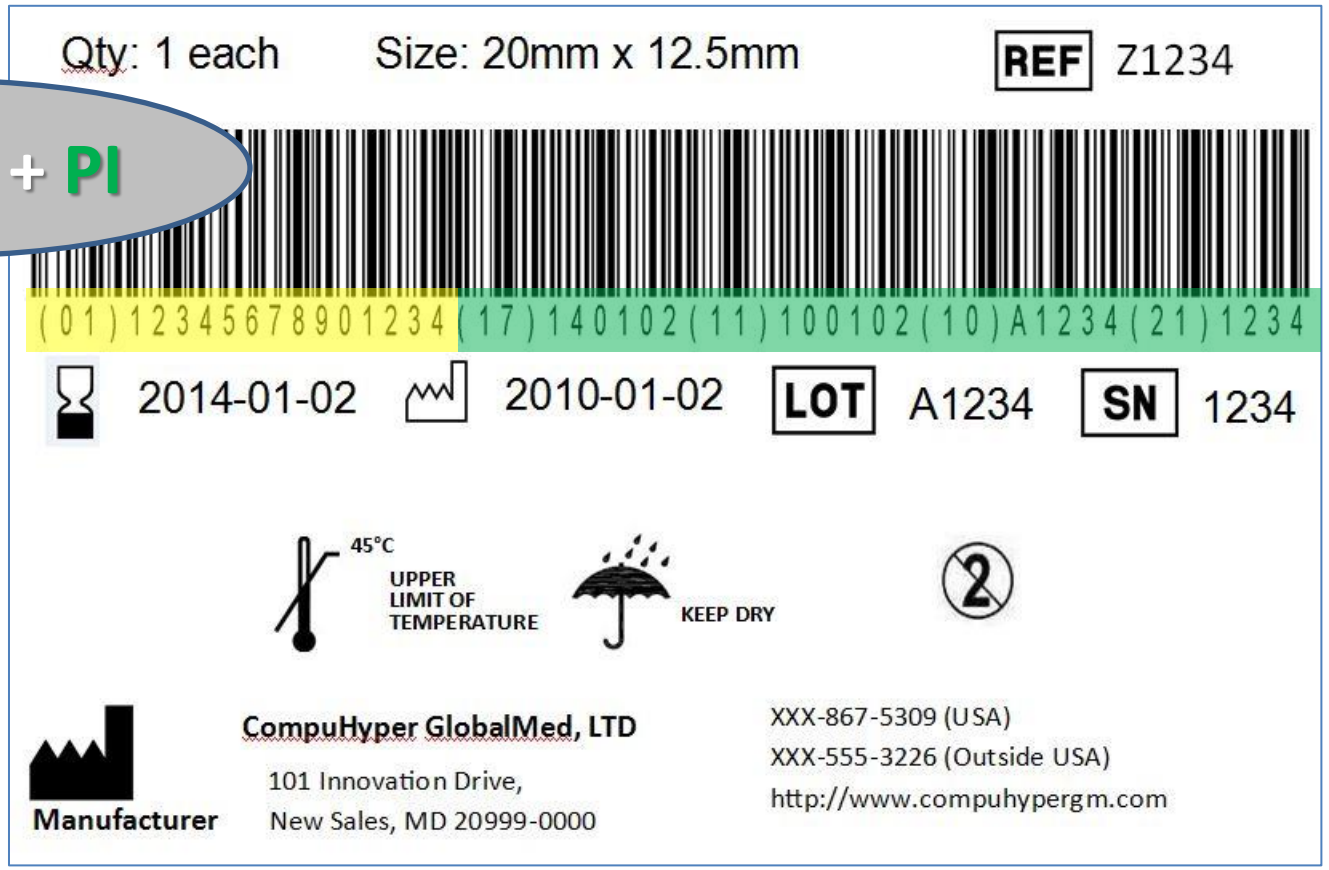
Strengthening our National System for Medical Device Postmarket Surveillance
http://www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf

What is a UDI?

Found on the device label, packaging or, in some cases, on the device itself

Both in plain text and machine readable format (AIDC)

UDI = DI + PI



GUDID Global Unique Device Identification Database

- Repository of key device identification information
- Contains ONLY the DI; PIs are not submitted to or stored in the GUDID
  - Contains only PI flags to indicate which PI attribute(s) are on the device label

Compliance Dates for UDI Requirements

Device	Label/GUDID/Date Format	Direct Mark (When Required)
Class III (including class III LS/LS)[1] Devices licensed under the PHS Act	September 24, 2014	Class III LS/LS devices must bear a permanent UDI by September 24, 2015 All other class III devices must bear a permanent UDI by September 24, 2016
Implantable (class II, class I & unclassified)	September 24, 2015	N/A
LS/LS[1] (class II, class I & unclassified)	September 24, 2015	September 24, 2015
Class II (other than I/LS/LS)	September 24, 2016	September 24, 2018
Class I or unclassified (other than I/LS/LS)	September 24, 2018	September 24, 2020

Link: Details on Compliance Dates

UDI

- 3 issuing agencies and 3 different formats
- The formats are complicated but have to have a mandatory part : Device Identifier, and potentially one or more of the following parts called Production Identifiers:
  - Serial Number, Lot, Manufacture Date, Expiration Date, Donation Identifier
  - There could be other parts in an identifier , such as activation code, version
- There is human readable version and a machine readable version of UDI
- UDI Formats by FDA-Accredited Issuing Agency May 7, 2014 (DOC - 132KB)

Scanning and Parsing of UDI

- A need for a common set of specifications or code that can be used by scanners to read, parse the UDI and ensure the following parts that uniquely identify the device in clinical setting are fetched and formulate a string to be used in EHR and other healthcare systems

GUDID Resources online

- CDRH Learn with GUDID Overview
- Guidance - Global Unique Device Identification Database (GUDID) - June 27, 2014 (PDF - 2.8MB)
- HL7 SPL Implementation Files – January 13, 2015 (ZIP - 1.8MB)
- GUDID Data Elements Reference Table - May 1, 2015 (XLS - 104KB)
- UDI Formats by FDA-Accredited Issuing Agency May 7, 2014 (DOC - 132KB)
- GUDID User Manual -- May 2014 (PDF - 2.2MB)

Reference Slides

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FDA TOOLS AND RESOURCES

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

cervical disc

- cervical total disc replacement prosthesis
- prestige® lp **cervical disc** system
- bryan® **cervical disc** system
- prestige® **cervical disc** system

ABOUT

The **Global** key device identification information submitted to the FDA about medical devices that have **Unique Device Identifiers (UDI)**.

The FDA is establishing the unique device identification system to adequately identify devices sold in the U.S. from manufacturing through distribution to patient use. You can use AccessGUDID to search for specific medical devices or download all the GUDID data at once.

MORE INFO

ABOUT UDI

ABOUT GUDID

NEWS

AccessGUDID News

Posted: June 2, 2015

Download the latest full releases and update files provided to the NLM by the FDA.

HELP

Help using AccessGUDID

Searching AccessGUDID

Downloading Release Files

NLM Web Guidelines

Still Need Help?

FDA TOOLS AND RESOURCES

FDA UDI Home

FDA Medical Devices Home

Report a Device Problem (MedWatch)

Device Recalls

Device Safety Communications

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IDENTIFY YOUR MEDICAL DEVICE

cervical disc

SEARCH RESULTS FOR: cervical disc (784 results)

EXPORT RESULTS

FILTERS | SORT BY | 10 RESULTS PER PAGE | < PAGE 1 >

- Company Name
- Brand Name
- GMDN Term
- FDA Product Code Name
- FDA Product Code
- Device Packaged as Sterile
- Sterilization Prior To Use
- Issuing Agency

PRESTIGE® Cervical Disc System - 00613994129215
DISC 6961460 CERVICAL DISC 6MM X 14MM
Company Name: MEDTRONIC SOFAMOR DANEK, INC. Model Number: 6961460

PRESTIGE® Cervical Disc System - 00613994129222
DISC 6961660 CERVICAL DISC 6MM X 16MM
Company Name: MEDTRONIC SOFAMOR DANEK, INC. Model Number: 6961660

PRESTIGE® Cervical Disc System - 00613994129239
DISC 6961670 CERVICAL DISC 7MM X 16MM
Company Name: MEDTRONIC SOFAMOR DANEK, INC. Model Number: 6961670

PRESTIGE® Cervical Disc System - 00613994129253
DISC 6961870 CERVICAL DISC 7MM X 18MM

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EXPORT RESULTS
XML
CSV
XLS
JSON

FILTERS | SORT BY | 10 RESULTS PER PAGE | < PAGE

- Company Name
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PRESTIGE® Cervical Disc System - 00613994129215
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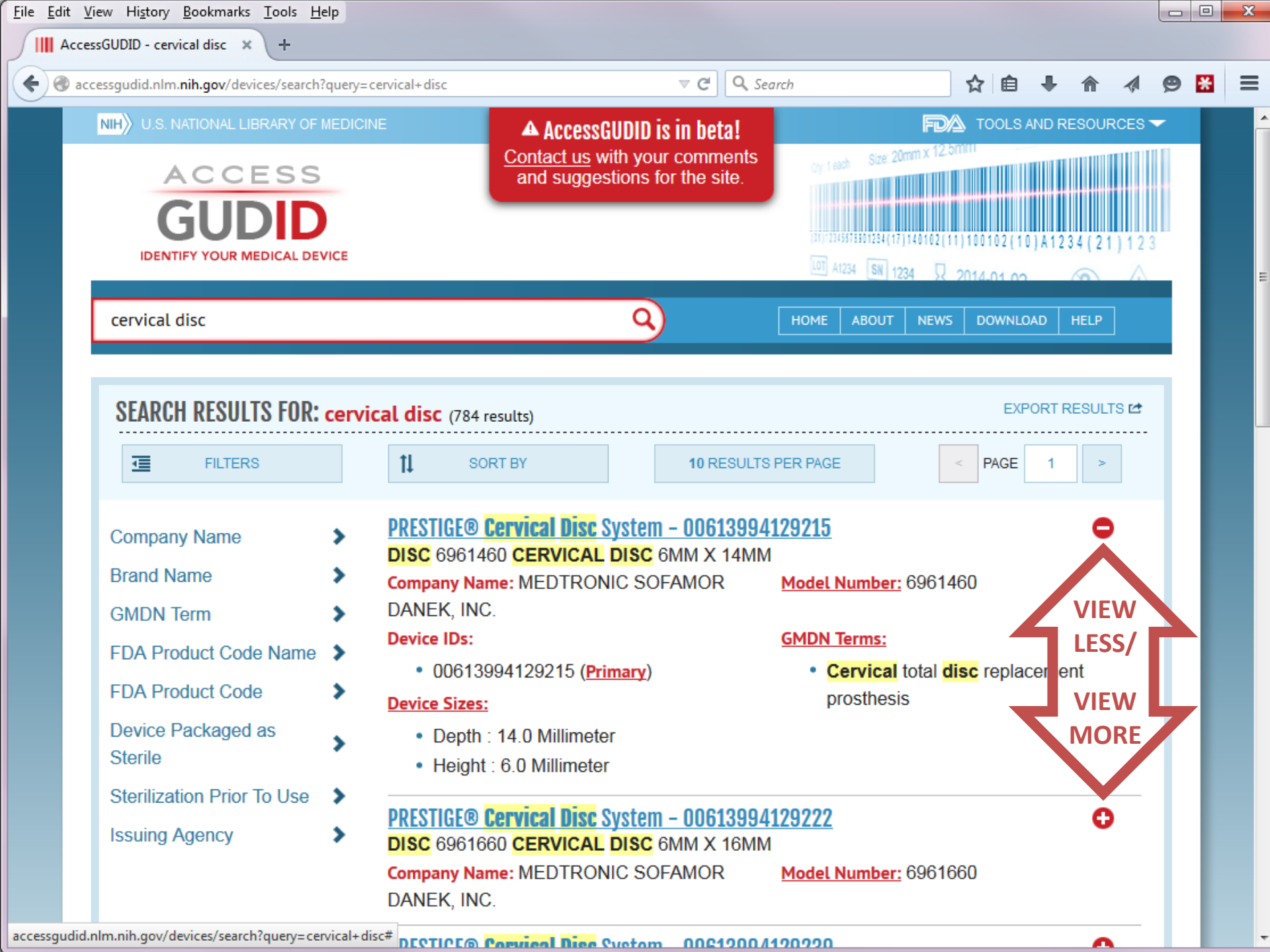
PRESTIGE® Cervical Disc System - 00613994129239
DISC 6961670 CERVICAL DISC 7MM X 16MM
Company Name: MEDTRONIC SOFAMOR DANEK, INC. Model Number: 6961670

PRESTIGE® Cervical Disc System - 00613994129253
DISC 6961870 CERVICAL DISC 7MM X 18MM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PAGE 1
Company Name
Brand Name
GMDN Term
FDA Product Code Name
FDA Product Code
Device Packaged as Sterile
Sterilization Prior To Use
Issuing Agency
PRESTIGE® Cervical Disc System - 00613994129215
DISC 6961460 CERVICAL DISC 6MM X 14MM
Company Name: MEDTRONIC SOFAMOR DANEK, INC.
Model Number: 6961460
Device IDs:
00613994129215 (Primary)
GMDN Terms:
Cervical total disc replacement prosthesis
Device Sizes:
Depth : 14.0 Millimeter
Height : 6.0 Millimeter
VIEW LESS/ VIEW MORE
PRESTIGE® Cervical Disc System - 00613994129222
DISC 6961660 CERVICAL DISC 6MM X 16MM
Company Name: MEDTRONIC SOFAMOR DANEK, INC.
Model Number: 6961660
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cervical disc

SEARCH RESULTS FOR: cervical disc (784 results)

EXPORT RESULTS

FILTERS | SORT BY | 10 RESULTS PER PAGE | < PAGE 1 >

- Company Name
- Brand Name
- GMDN Term
- FDA Product Code Name
- FDA Product Code
- Device Packaged as Sterile
- Sterilization Prior To Use
- Issuing Agency

PRESTIGE® Cervical Disc System - 00613994129215

DISC 6961460 **CERVICAL DISC** 6MM X 14MM

Company Name: MEDTRONIC SOFAMOR DANEK, INC.

Model Number: 6961460

Device IDs:

- 00613994129215 (Primary)

GMDN Terms:

- **Cervical** total **disc** replacement prosthesis

Device Sizes:

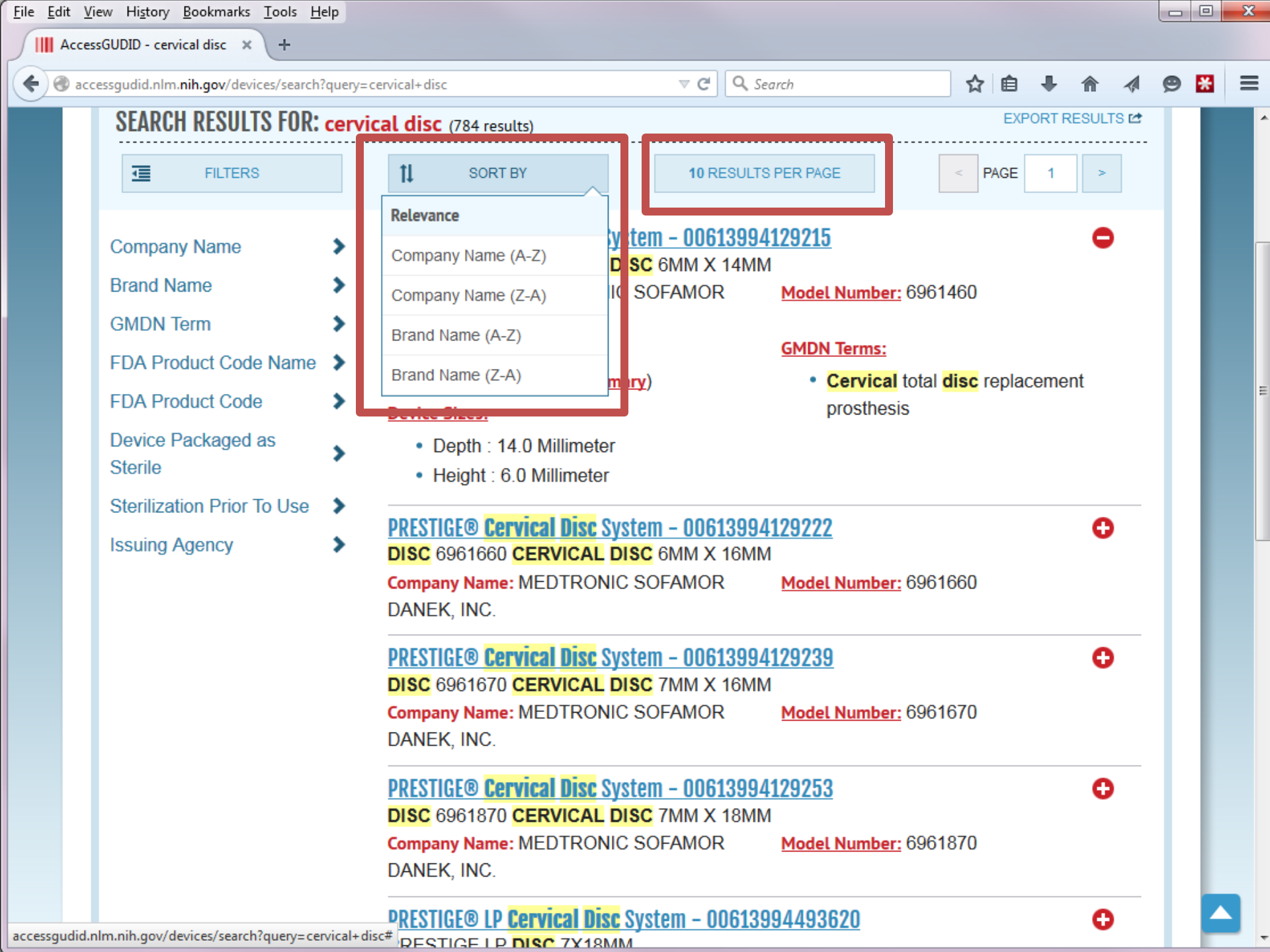
- Depth : 14.0 Millimeter
- Height : 6.0 Millimeter

PRESTIGE® Cervical Disc System - 00613994129222

DISC 6961660 **CERVICAL DISC** 6MM X 16MM

Company Name: MEDTRONIC SOFAMOR DANEK, INC.

Model Number: 6961660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Search
SEARCH RESULTS FOR: cervical disc (784 results)
EXPORT RESULTS
FILTERS
SORT BY
10 RESULTS PER PAGE
PAGE 1
Relevance
Company Name (A-Z)
Company Name (Z-A)
Brand Name (A-Z)
Brand Name (Z-A)
Company Name
Brand Name
GMDN Term
FDA Product Code Name
FDA Product Code
Device Packaged as Sterile
Sterilization Prior To Use
Issuing Agency
tem - 00613994129215
SC 6MM X 14MM
SOFAMOR
Model Number: 6961460
GMDN Terms:
Cervical total disc replacement prosthesis
Depth : 14.0 Millimeter
Height : 6.0 Millimeter
PRESTIGE® Cervical Disc System - 00613994129222
DISC 6961660 CERVICAL DISC 6MM X 16MM
Company Name: MEDTRONIC SOFAMOR DANEK, INC.
Model Number: 6961660
PRESTIGE® Cervical Disc System - 00613994129239
DISC 6961670 CERVICAL DISC 7MM X 16MM
Company Name: MEDTRONIC SOFAMOR DANEK, INC.
Model Number: 6961670
PRESTIGE® Cervical Disc System - 00613994129253
DISC 6961870 CERVICAL DISC 7MM X 18MM
Company Name: MEDTRONIC SOFAMOR DANEK, INC.
Model Number: 6961870
PRESTIGE® LP Cervical Disc System - 00613994493620
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Search

SEARCH RESULTS FOR: cervical disc (784 results)

EXPORT RESULTS

FILTERS | SORT BY | 10 RESULTS PER PAGE | < PAGE 1 >

Company Name

- AESCULAP IMPLANT SYSTEMS, LLC (3)
- ALPHATEC SPINE, INC. (49)
- Innovasis, Inc. (7)
- L&K Biomed Co., Ltd. (265)
- LDR Spine Usa, Inc. (43)
- MEDTRONIC SOFAMOR DANEK, INC. (81)
- Medacta International SA (60)
- Nuvasive, Inc. (24)

Brand Name

GMDN Term

FDA Product Code Name

FDA Product Code

Device Packaged as Sterile

PRESTIGE® Cervical Disc System - 00613994129215

DISC 6961460 **CERVICAL DISC** 6MM X 14MM

Company Name: MEDTRONIC SOFAMOR DANEK, INC.

Model Number: 6961460

Device IDs:

- 00613994129215 (Primary)

GMDN Terms:

- **Cervical** total **disc** replacement prosthesis

Device Sizes:

- Depth : 14.0 Millimeter
- Height : 6.0 Millimeter

PRESTIGE® Cervical Disc System - 00613994129222

DISC 6961660 **CERVICAL DISC** 6MM X 16MM

Company Name: MEDTRONIC SOFAMOR DANEK, INC.

Model Number: 6961660

PRESTIGE® Cervical Disc System - 00613994129239

DISC 6961670 **CERVICAL DISC** 7MM X 16MM

Company Name: MEDTRONIC SOFAMOR DANEK, INC.

Model Number: 6961670

PRESTIGE® Cervical Disc System - 00613994129253

DISC 6961870 **CERVICAL DISC** 7MM X 18MM

Company Name: MEDTRONIC SOFAMOR DANEK, INC.

Model Number: 6961870

PRESTIGE® LP Cervical Disc System - 00613994493620

PRESTIGE LP **DISC** 7X18MM

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ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

DEVICE: PRESTIGE® Cervical Disc System (00613994129215)

DOWNLOAD: XML | JSON PRINT

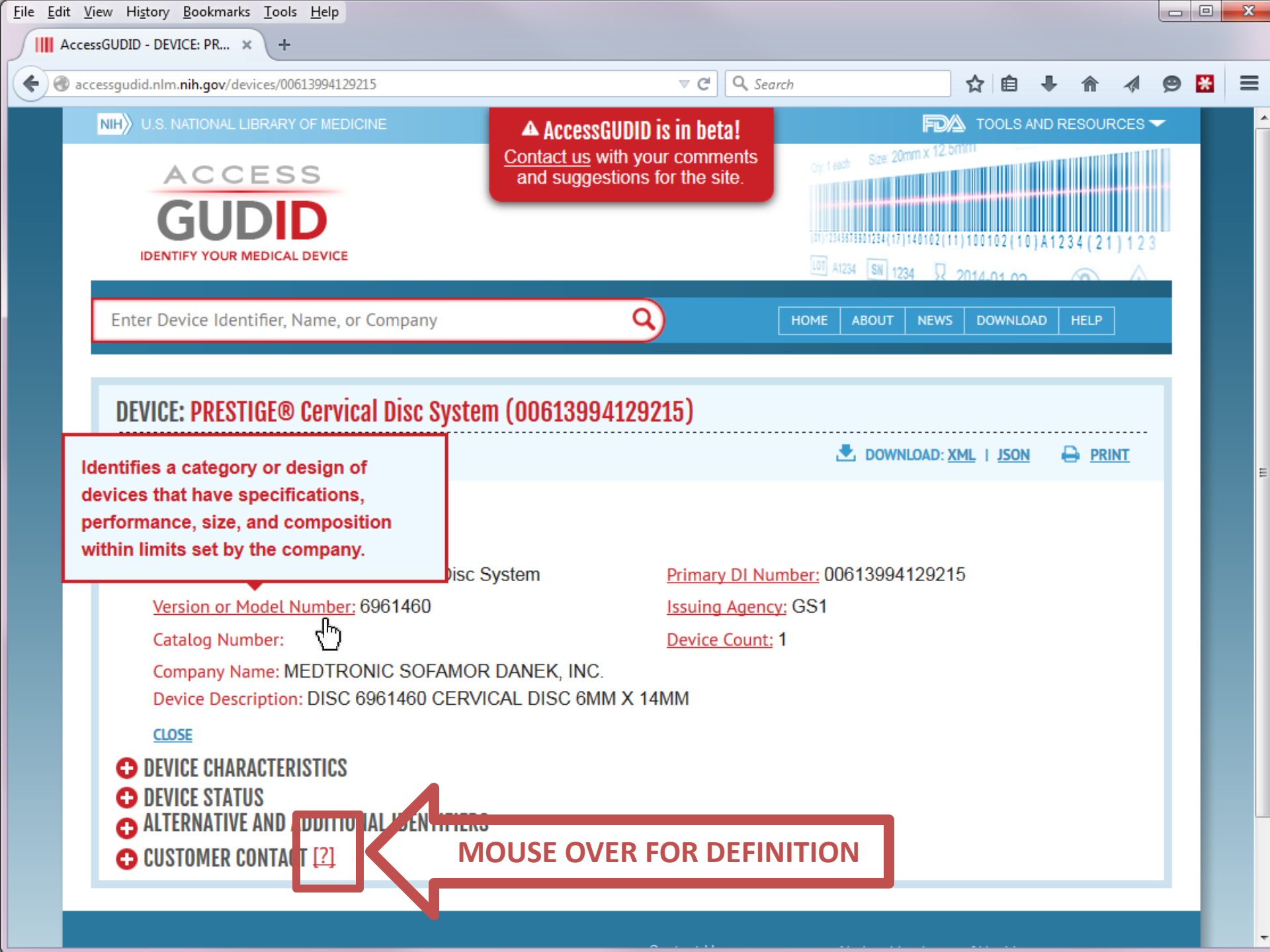
VIEW ALL SECTIONS | CLOSE ALL SECTIONS

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: PRESTIGE® Cervical Disc System
Primary DI Number: 00613994129215
Version or Model Number: 6961460
Issuing Agency: GS1
Catalog Number:
Device Count: 1
Company Name: MEDTRONIC SOFAMOR DANEK, INC.
Device Description: DISC 6961460 CERVICAL DISC 6MM X 14MM

CLOSE

DEVICE CHARACTERISTICS
DEVICE STATUS
ALTERNATIVE AND ADDITIONAL IDENTIFIERS
CUSTOMER CONTACT [?]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Enter Device Identifier, Name, or Company
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DEVICE: PRESTIGE® Cervical Disc System (00613994129215)
DOWNLOAD: XML | JSON
PRINT
Identifies a category or design of devices that have specifications, performance, size, and composition within limits set by the company.
Primary DI Number: 00613994129215
Version or Model Number: 6961460
Issuing Agency: GS1
Catalog Number:
Device Count: 1
Company Name: MEDTRONIC SOFAMOR DANEK, INC.
Device Description: DISC 6961460 CERVICAL DISC 6MM X 14MM
CLOSE
DEVICE CHARACTERISTICS
DEVICE STATUS
CUSTOMER CONTACT [?]
MOUSE OVER FOR DEFINITION

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ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

DEVICE: PRESTIGE® Cervical Disc System (00613994129215)

DOWNLOAD: XML | JSON PRINT

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

VIEW ALL / CLOSE ALL

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: PRESTIGE® Cervical Disc System
Primary DI Number: 00613994129215
Version or Model Number: 6961460
Issuing Agency: GS1
Catalog Number:
Device Count: 1
Company Name: MEDTRONIC SOFAMOR DANEK, INC.
Device Description: DISC 6961460 CERVICAL DISC 6MM X 14MM

CLOSE

DEVICE CHARACTERISTICS
DEVICE STATUS
ALTERNATIVE AND ADDITIONAL IDENTIFIERS
CUSTOMER CONTACT [?]

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DEVICE: PRESTIGE® Cervical Disc System (00613994129215)

DOWNLOAD: XML | JSON PRINT

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: PRESTIGE® Cervical Disc System
Primary DI Number: 00613994129215
Version or Model Number: 6961460
Issuing Agency: GS1
Catalog Number:
Device Count: 1
Company Name: MEDTRONIC SOFAMOR DANEK, INC.
Device Description: DISC 6961460 CERVICAL DISC 6MM X 14MM

CLOSE

DEVICE CHARACTERISTICS

What MRI safety information does the labeling contain?	Labeling does not contain MRI Safety Information
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437):	No
Device labeled as "Not made with natural rubber latex":	No

Device labeled as "Not made with natural rubber latex":	No
For Single-Use:	Yes
Prescription Use (Rx):	Yes
Over the Counter (OTC):	No
Kit:	No
Combination Product:	No
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P):	No

GMDN [?]

GMDN Names and Definitions: © Copyright GMDN Agency 2015. Reproduced with Permission from the GMDN Agency.

GMDN Preferred Term Name	GMDN Definition
Cervical total disc replacement prosthesis	A sterile implantable device designed to replace most or all of a dysfunctional intervertebral disc in the cervical spine. It is typically made of metal or plastic-like (biopolymer) materials, or a combination of the two. It most commonly has a two-plate design, one plate attaching to the vertebra above and the other to the vertebra below. The device is intended to facilitate motion usually through the sliding action of its smooth surfaces.

CLOSE

FDA PRODUCT CODE [?]

FDA PRODUCT CODE [?]

Product Code	Product Code Name
MJO	PROSTHESIS, INTERVERTEBRAL DISC

CLOSE

STERILIZATION

Device Packaged as Sterile: Yes

Requires Sterilization Prior to Use: No

Sterilization Method
No Sterilization Methods Found

CLOSE

STORAGE AND HANDLING [?]

Storage and Handling
No storage/handling found

CLOSE

CLINICALLY RELEVANT SIZE [?]

Size Type Text
Depth: 14.0 Millimeter
Height: 6.0 Millimeter

CLOSE

CLOSE

DEVICE STATUS

Commercial Distribution Status: In Commercial Distribution

DI Record Publish Date: September 23, 2014

Commercial Distribution End Date:

CLOSE

ALTERNATIVE AND ADDITIONAL IDENTIFIERS

PACKAGE DI [?]

Package DI Number	Quantity per Package	Contains DI Package	Package Discontinue Date	Package Status
No Package DIs found				

CLOSE

SECONDARY DI [?]

Issuing Agency [?]	Secondary DI Number
No Secondary DIs found	

CLOSE

UNIT OF USE DI [?]

Unit of Use DI Number: No Unit of Use DI Numbers Found

CLOSE

DIRECT MARKING (DM) [?]

Device Subject to Direct Marking (DM), but Exempt: No

Unit of Use DI Number: No Unit of Use DI Numbers Found

CLOSE

DIRECT MARKING (DM) [?]

Device Subject to Direct Marking (DM), but Exempt: No

DM DI Different from Primary DI: No

DM DI Number: None

CLOSE

PRODUCTION IDENTIFIER(S) IN UDI [?]

Lot or Batch Number: Yes

Serial Number: No

Expiration Date: No

Manufacturing Date: No

Donation Identification Number: No

CLOSE

CUSTOMER CONTACT [?]

Phone: +1(800)633-8766

Email: Corporate.UDI@medtronic.com

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Advanced Search and Web Services are coming soon!

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- Did AccessGUDID help you find an answer to your device related question?

Full E-mail Address (required for a reply)

First Name

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