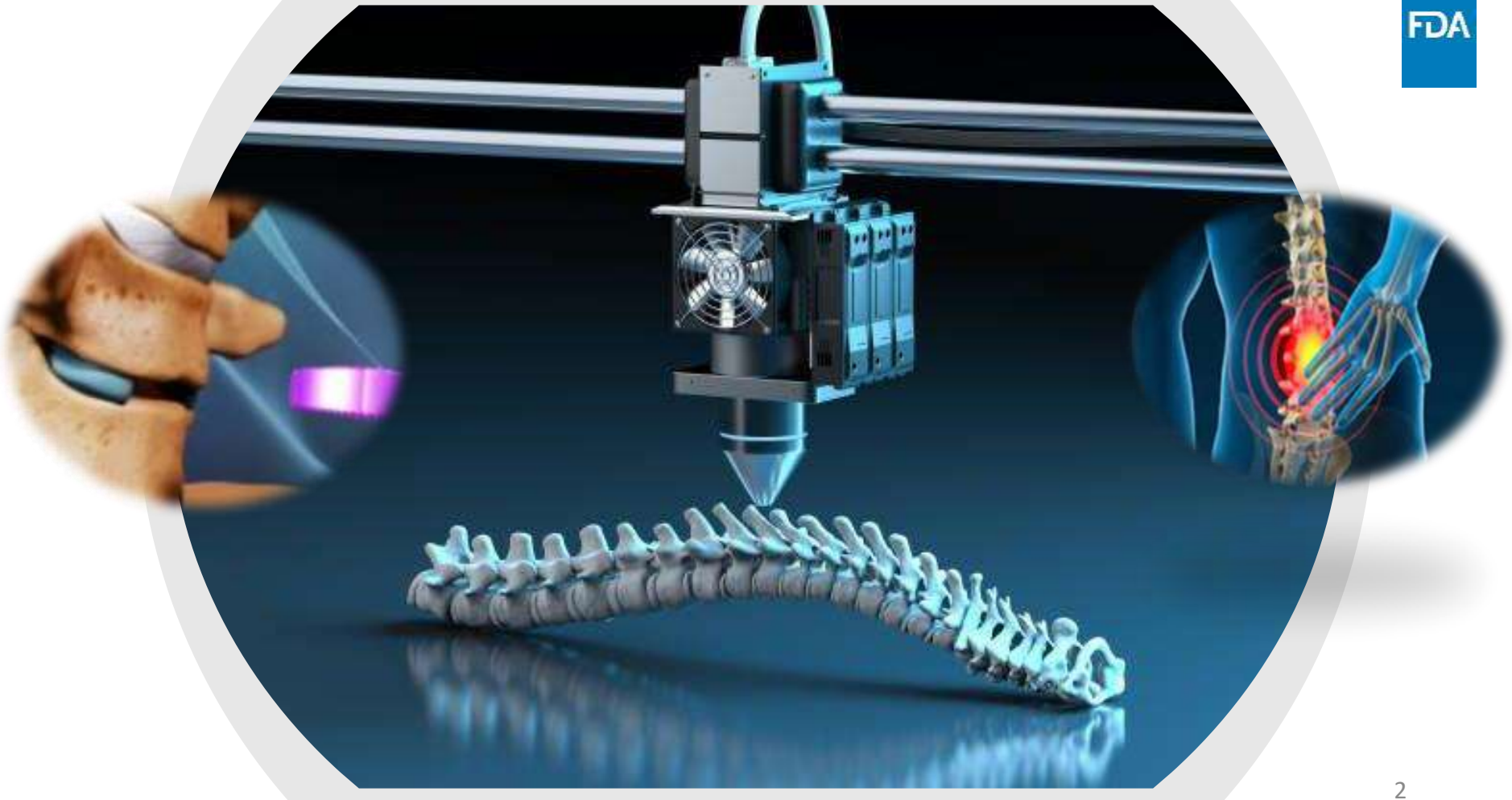
The 510(k) Program: How to Determine an Effective Predicate Device

FDA Small Business Regulatory Education for Industry (REdI)

July 21, 2021

Melissa Hall

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



Learning Objectives

1. Provide an overview of the 510(k) process
2. Describe predicate device and key factors to consider when choosing a predicate
3. Apply key factors and consideration for selecting a predicate through a case study

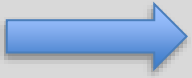
Overview:
The 510(k) Process

Device Advice: Premarket Notification 510(k)

What is a 510(k)?

- A type of premarket submission
- Demonstrate safety and effectiveness
- Substantial equivalence (SE) to a legally-marketed device

What is a Predicate Device?

- Predicate device  Legally-marketed device
- A legally-marketed device:
  - was legally marketed prior to May 28, 1976 (preamendments device)
  - has been reclassified from Class III to Class II or I
  - has been found substantially equivalent (SE) through the 510(k) process (includes De Novo)

The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

Predicate Device Concepts

Multiple Predicate:

- Combine features from two or more predicate devices with the same intended use
- Market a device with more than one intended use
- More than one indication for use under the same intended use

Reference Device:

- Need to get through Decision Point 4 on the Flowchart using a single predicate
- May be used to support scientific methodology or standard reference values at Decision Point 5a.

What is the Purpose of a Predicate?

Lessen burden of proof of safety and effectiveness of device:

Intended Use	Design
Materials	Performance
Safety	Effectiveness
Biocompatibility	Labeling
Standards	Energy used or delivered

Substantial Equivalence

Your device is as safe and effective as the predicate

- **Same** intended use

AND

- Same or **different** technological characteristics
  - Do not raise different questions of safety and effectiveness
  - Information submitted to FDA demonstrates your device is as safe and effective as the legally marketed device

Knowledge Check

Can I claim substantial equivalence to a device that was granted marketing authorization via the De Novo classification process?

a. Yes
b. No
c. It depends

Device Advice: De Novo Classification Request

How to Choose Your Predicate Device

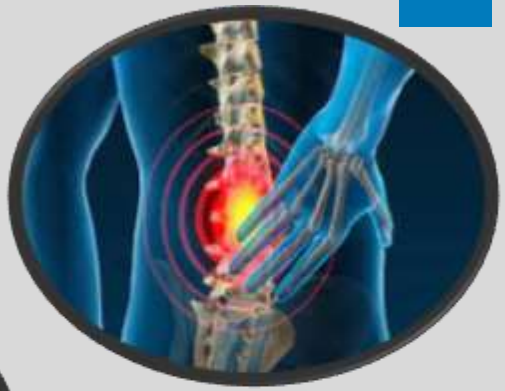
Steps for Selecting Valid Predicate

1. Identify Intended Use
2. Search Similar Products
3. Compare Technology
4. Compare Performance

Case Study:
Intervertebral Body Fusion Device

What are Intervertebral Body Fusion Devices (IBFs/Cages)

A device that is inserted into the intervertebral body space of the cervical thoracic, or lumbosacral spine, and is intended for intervertebral body fusion.



1 Intended Use

Intended Use	Indications for use
The general purpose of the device or its function. This includes the indications for use.	Describes the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended.

Example:

Indications for Use

The Bluestone Synergy cervical (Slate Lavaflow) implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with cervical disc disease…

Steps for Selecting Valid Predicate

1. Identify Intended Use
2. Search Similar Products
3. Compare Technology
4. Compare Performance

2 Searching Similar Products

- Trade names of similar devices
- Manufacturer(s) of similar devices
- 510(k) numbers for similar devices
- Product codes
- Classification regulation

Medical Device Databases

Device Advice

Webpages:

- Classify your Medical Device
- How to Find and Effectively Use Predicate Devices

CDRH Learn:

- How is My Medical Device Classified?

Device Advice: Comprehensive Regulatory Assistance

2

Product Classification

FDA Home › Medical Devices › Databases

This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA Premarket Review organizations, and other regulatory information.

learn more...

Search Database

Help Download Files

Device

Product Code

Review Panel

Regulation Number

Submission Type

Third Party Elligible

Implanted Device

Life-Sustain/Support Device

Device Class

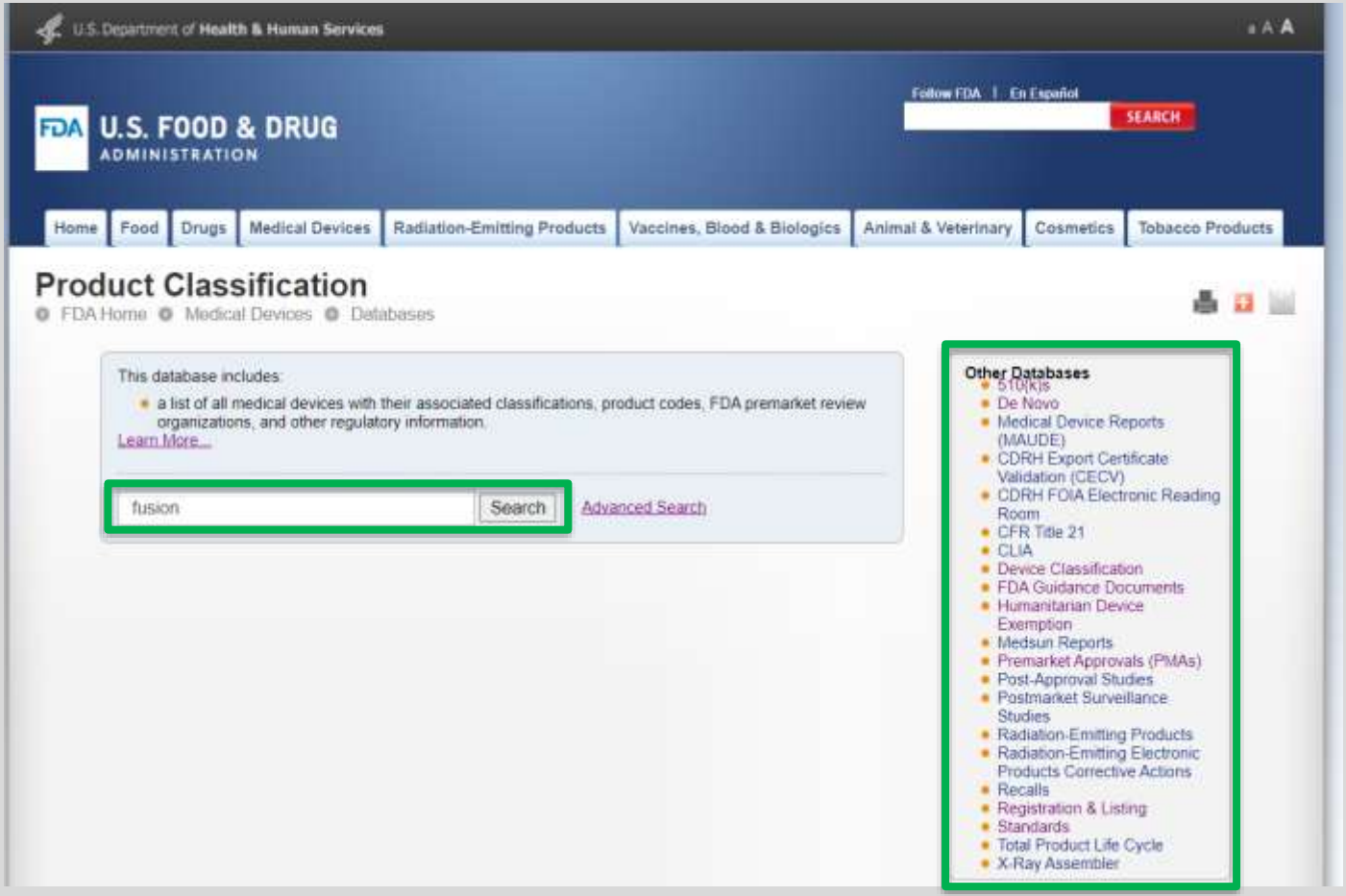
Summary Malfunction Reporting

Go to Quick Search

Clear Form

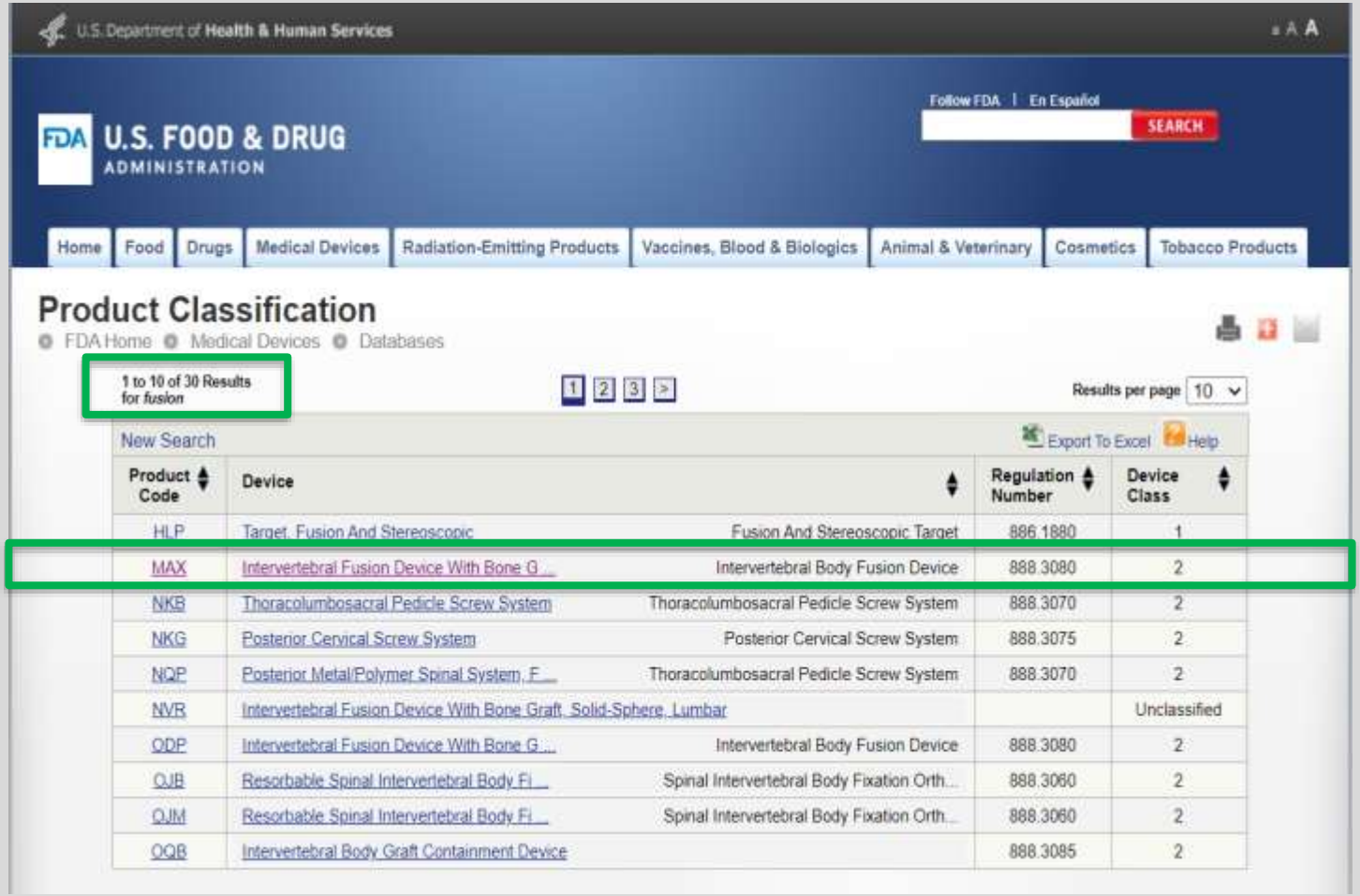
search

2

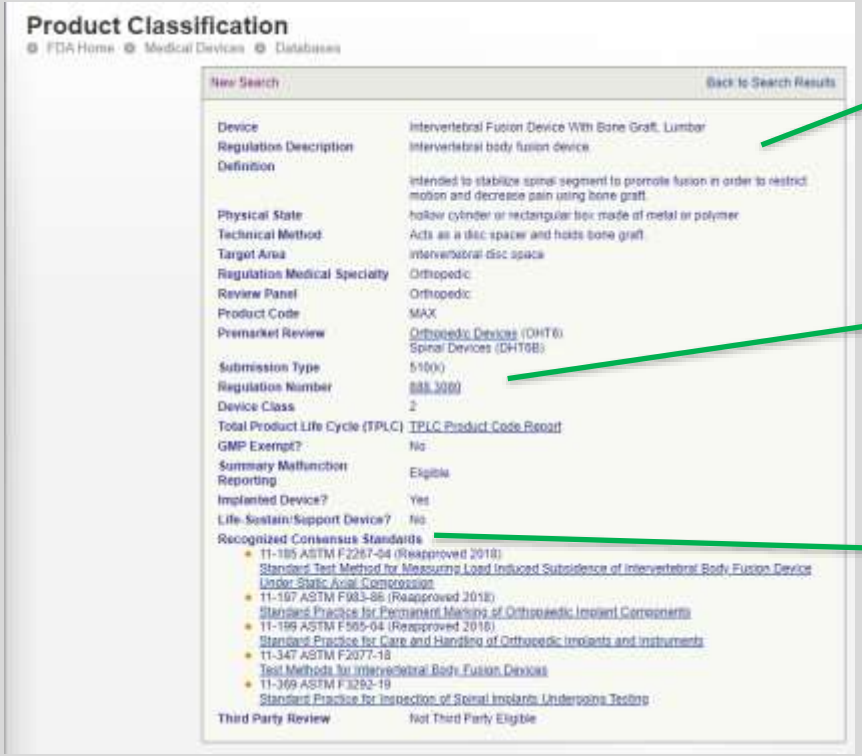


www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/pcdsimplesearch.cfm

2


U.S. Department of Health & Human Services
U.S. FOOD & DRUG ADMINISTRATION
Follow FDA | En Español
SEARCH
Home
Food
Drugs
Medical Devices
Radiation-Emitting Products
Vaccines, Blood & Biologics
Animal & Veterinary
Cosmetics
Tobacco Products
Product Classification
FDA Home
Medical Devices
Databases
1 to 10 of 30 Results for fusion
1 2 3 >
Results per page 10
New Search
Export To Excel
Help
Product Code
Device
Regulation Number
Device Class
HLP Target, Fusion And Stereoscopic Fusion And Stereoscopic Target 886.1880 1
MAX Intervertebral Fusion Device With Bone G... Intervertebral Body Fusion Device 888.3080 2
NKB Thoracolumbosacral Pedicle Screw System Thoracolumbosacral Pedicle Screw System 888.3070 2
NKG Posterior Cervical Screw System Posterior Cervical Screw System 888.3075 2
NQP Posterior Metal/Polymer Spinal System, F... Thoracolumbosacral Pedicle Screw System 888.3070 2
NVR Intervertebral Fusion Device With Bone Graft, Solid-Sphere, Lumbar Unclassified
ODP Intervertebral Fusion Device With Bone G... Intervertebral Body Fusion Device 888.3080 2
OJB Resorbable Spinal Intervertebral Body Fi... Spinal Intervertebral Body Fixation Orth... 888.3060 2
OJM Resorbable Spinal Intervertebral Body Fi... Spinal Intervertebral Body Fixation Orth... 888.3060 2
OQB Intervertebral Body Graft Containment Device 888.3085 2

2 Intervertebral Fusion Device



Product Classification

FDA Home ⚙ Medical Devices ⚙ Databases

New Search | Back to Search Results

Device	Intervertebral Fusion Device With Bone Graft, Lumbar
Regulation Description	Intervertebral body fusion device.
Definition	Intended to stabilize spinal segment to promote fusion in order to restrict motion and decrease pain using bone graft.
Physical State	hollow cylinder or rectangular box made of metal or polymer
Technical Method	Acts as a disc spacer and holds bone graft
Target Area	intervertebral disc space
Regulation Medical Specialty	Orthopedic
Review Panel	Orthopedic
Product Code	MAX
Premarket Review	Orthopedic Devices (OHT6) Spinal Devices (OHT6B)
Submission Type	510(k)
Regulation Number	888.3080
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	Yes
Life-Sustain/Support Device?	No
Recognized Consensus Standards	• 11-185 ASTM F2267-04 (Reapproved 2018) Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression • 11-197 ASTM F983-86 (Reapproved 2018) Standard Practice for Permanent Marking of Orthopaedic Implant Components • 11-199 ASTM F565-04 (Reapproved 2018) Standard Practice for Care and Handling of Orthopedic Implants and Instruments • 11-347 ASTM F2077-18 Test Methods for Intervertebral Body Fusion Devices • 11-369 ASTM F3282-19 Standard Practice for Inspection of Spinal Implants Undergoing Testing
Third Party Review	Not Third Party Eligible

Device	Intervertebral Fusion Device With Bone Graft, Lumbar
Regulation Description	Intervertebral body fusion device.
Definition	Intended to stabilize spinal segment to promote fusion in order to restrict motion and decrease pain using bone graft.

Submission Type	510(k)
Regulation Number	888.3080
Device Class	2

Recognized Consensus Standards

- 11-185 ASTM F2267-04 (Reapproved 2018)
  Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
- 11-197 ASTM F983-86 (Reapproved 2018)

[FDA Guidance Document Database]

2 Code of Federal Regulation (CFR)

New Search | Help | More About 21CFR

See Related Information

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2020]
[CITE: 21CFR888.3080]

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

PART 888 -- ORTHOPEDIC DEVICES

Subpart D - Prosthetic Devices

Sec. 888.3080 Intervertebral body fusion device.

(a) *Identification.* An intervertebral body fusion device is an implanted single or multiple component spinal device made from a variety of materials, including titanium and polymers. The device is inserted into the intervertebral body space of the cervical or lumbosacral spine, and is intended for intervertebral body fusion.

(b) *Classification.* (1) Class II (special controls) for intervertebral body fusion devices that contain bone grafting material. The special control is the FDA guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device." See § 888.1(e) for the availability of this guidance document.

(2) Class III (premarket approval) for intervertebral body fusion devices that include any therapeutic biologic (e.g., bone morphogenic protein). Intervertebral body fusion devices that contain any therapeutic biologic require premarket approval.

(c) *Date premarket approval application (PMA) or notice of product development protocol (PDP) is required.* Devices described in paragraph (b)(2) of this section shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[72 FR 32172, June 12, 2007]

[Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program]

2

510(k) Premarket Notification

FDA Home ● Medical Devices ● Databases

A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act) that is not subject to premarket approval.

Learn more...

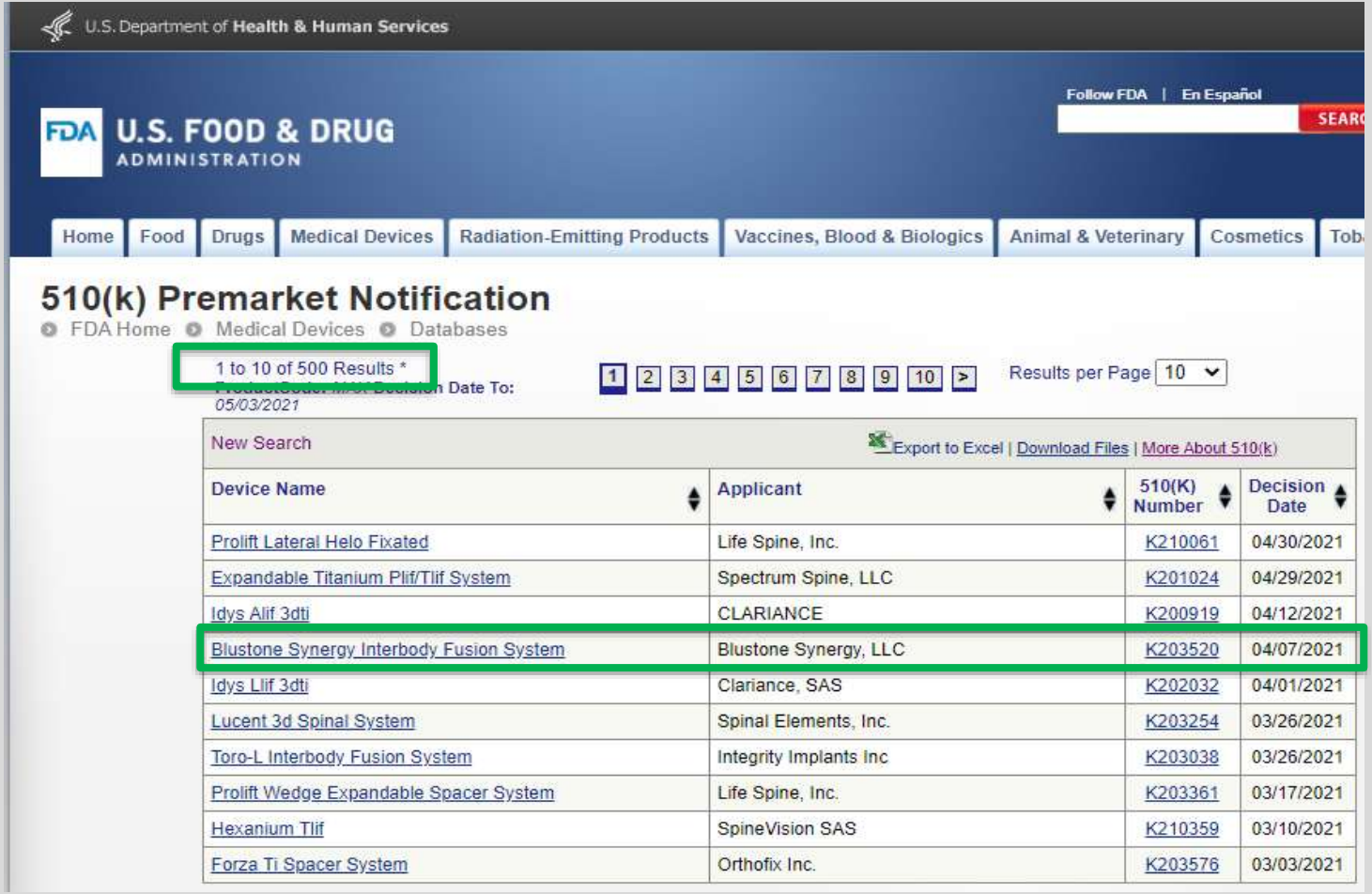
Search Database

Help Download Files

510K Number		Type	
Product Code	MAX		
Center			
Combination Products			
Applicant Name			
Cleared/Approved In Vitro Products			
Device Name			
Redacted FOIA 510(k)			
Panel			
Third Party Reviewed			
Decision			
Decision Date		to	
Clinical Trials			
Sort by	Decision Date (descending)		

Quick Search Clear Form Search

2



Device Name	Applicant	510(K) Number	Decision Date
Prolift Lateral Helo Fixated	Life Spine, Inc.	K210061	04/30/2021
Expandable Titanium Plif/Tlif System	Spectrum Spine, LLC	K201024	04/29/2021
Idys Alif 3dti	CLARIANCE	K200919	04/12/2021
Blustone Synergy Interbody Fusion System	Blustone Synergy, LLC	K203520	04/07/2021
Idys Llif 3dti	Clariance, SAS	K202032	04/01/2021
Lucent 3d Spinal System	Spinal Elements, Inc.	K203254	03/26/2021
Toro-L Interbody Fusion System	Integrity Implants Inc	K203038	03/26/2021
Prolift Wedge Expandable Spacer System	Life Spine, Inc.	K203361	03/17/2021
Hexanium Tlif	SpineVision SAS	K210359	03/10/2021
Forza Ti Spacer System	Orthofix Inc.	K203576	03/03/2021

2

Device Classification Name	Intervertebral Fusion Device With Bone Graft, Cervical
510(K) Number	K203520
Device Name	Blustone Synergy Interbody Fusion System
Applicant	Blustone Synergy, LLC 5520 Ventana Ct Pueblo, CO 81005
Applicant Contact	Tom Gentry
Correspondent	MRC Global, LLC 9085 E. Mineral Cir., Suite 110 Centennial, CO 80112
Correspondent Contact	Christine Scifert
Regulation Number	888.3080
Classification Product Code	ODP
Subsequent Product Code	MAX
Date Received	12/01/2020
Decision Date	04/07/2021
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Orthopedic
510k Review Panel	Orthopedic
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Re: K203520
Trade/Device Name: Blustone Synergy Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: February 5, 2021
Received: February 10, 2021

Dear Christine Scifert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K203520

K203520
Page 1 of 2

510(k) Summary
Blustone Synergy Interbody Fusion System
April 6, 2021

2

510(k) Summary
Blustone Synergy Interbody Fusion System
April 6, 2021

Company: Blustone Synergy, LLC.
5520 Ventana Ct.
Pueblo, CO 81005
Phone: (800) 232-9108

Company Contact: Tom Gentry
Admin Manager – Blustone Synergy, LLC
admin@blustonsynergy.com
760-992-6118

Official Correspondent: Christine Scifert – MRC Global, LLC
Christine.scifert@askmrcglobal.com
901-831-8053

Trade Name: Blustone Synergy Interbody Fusion System

Common Name: Intervertebral Fusion Device With Bone Graft, Cervical
Intervertebral Fusion Device With Bone Graft, Lumbar

Classification: Class II

Regulation Number: 21 CFR 888.3080 (Intervertebral body fusion device)

Panel: Orthopedic

Product Code: ODP, MAX

Device Description:
The Blustone Synergy Interbody Fusion System is composed of cervical and lumbar interbody fusion devices. The BluStone Synergy Slate Lavaflow System is a Titanium Plasma Coated cervical interbody fusion system comprised of parallel and 6° lordotic cages in two footprints with varying heights designed to accommodate patient anatomy, and may be implanted as a single device via an anterior approach. The Blustone Synergy Lumbar Interbody Lavaflow System is a Titanium Plasma Coated lumbar interbody fusion

Indications for Use:
BluStone Synergy Lumbar Interbody Lavaflow System (Basalt LAVAFLOW, Magma LAVAFLOW, Obsidian LAVAFLOW):
The Blustone Synergy lumbar (Lavaflow) implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two

Substantial Equivalence:
The subject Blustone Synergy Interbody Fusion System is substantially equivalent to the following predicate devices:

Primary Predicate:
- Blustone Synergy Interbody Fusion (K171893; S.E. 09/08/2017)

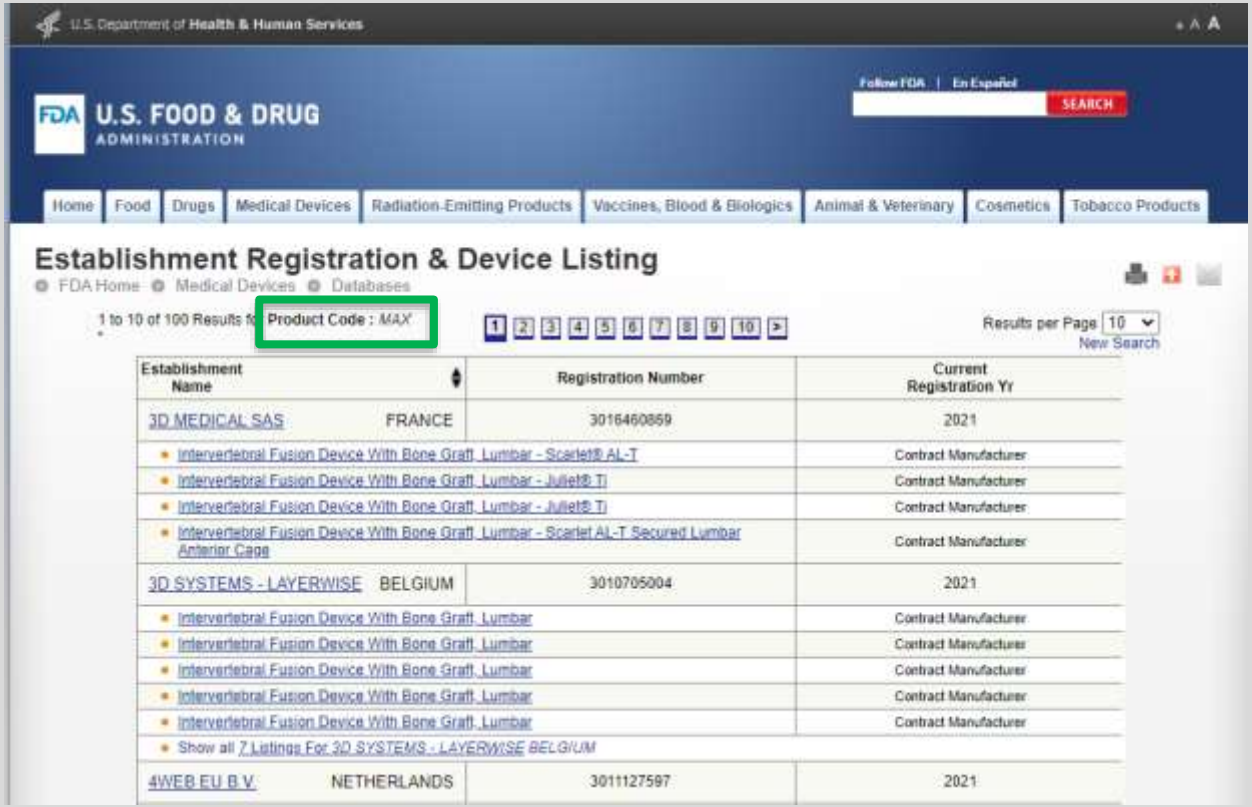
Performance Testing:
Mechanical testing, including expulsion, dynamic compression per ASTM F2077, and wear debris analysis per ASTM F1877 have been performed on the subject Blustone Synergy cervical interbody devices and the results have shown them to be substantially equivalent to the predicate interbody devices.

2

Freedom of Information Act (FOIA)

- FDA's Freedom of Information Homepage
- CDRH FOIA: How to Get Records from CDRH
- CDRH FOI Reference Sheet
- How to Make a FOIA Request
- CDRH FOIA Electronic Reading Room
- FOIA Fees

2 Search Registration and Listing Database



[Establishment Registration & Device Listing Database]

Steps for Selecting Valid Predicate

1. Search Similar Products
2. Identify Intended Use
3. Compare Technology
4. Compare Performance

3 Technological Characteristics

- Materials
- Design
- Energy Source
- Other Features

3 Compare Technological Features

	New Device	Predicate Device
Device Image		
Size	30x26mm, 6° 30x26mm, 10°	30x25mm, 5° 30x25mm,10°
Material	PEEK, Ti-6Al-4V	PEEK, Ti-6Al-4V
Unique Features	4 screws, coverplate	3 screws

Steps for Selecting Valid Predicate

1. Search Similar Products
2. Identify Intended Use
3. Compare Technology
4. Compare Performance

Performance Characteristics

- **Well-established scientific methods**
  - Guidance Documents
  - Standards
- **Safety and Performance Based Pathway**
- **Expected performance**
  - Medical Device Reporting (MDRs)
    - Manufacturer and User Facility Device Experience (MAUDE) database
  - Recalls, Market Withdrawals, & Safety Alerts

Knowledge Check

Which database is NOT useful for determining your predicate device?

a. Premarket Notification 510(k)
b. Registration & Listing
c. Standards
d. Product Classification

Summary

1. Discussed the 510(k) process and substantial equivalence.
2. Described what is a predicate device and key factors to consider when choosing a predicate.
3. Applied the resources available to determine your predicate through a case study example.

Resources

Resource Type	Resource Title	URL
FDA Guidance	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)]	www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k
FDA Guidance	Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program	www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program
Database	Medical Device Databases	www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
Video Training Modules	CDRH Learn	www.fda.gov/training-and-continuing-education/cdrh-learn
FDA Webpage	FDA's Freedom of Information Homepage	www.fda.gov/regulatory-information/freedom-information
Device Advice Webpage	Premarket Notification 510(k)	www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k
Device Advice Webpage	Classify your Medical Device	www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device
Device Advice Webpage	Device Advice: De Novo Classification Request	www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request

Questions


FDA
U.S. FOOD & DRUG
ADMINISTRATION