510(k) Summary

SEP 12 2011

Summary of 510(k) Safety and Effectiveness

Submitted By:	Intuitive Spine, LLC 16450-3 S. Tamiami Trail #112 Fort Myers, Florida 33908
Date:	July 27, 2011
Contact Person:	Jennifer Palinchik Development and Regulatory Consultant
Contact Telephone:	(440) 933-8850
Device Trade Name:	DISCOVERY
Device Classification Name:	Intervertebral Body Fusion Device with Bone Graft,
Cervical Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number:	888.3080
Product Code:	ODP
Predicate Device:	LDR Spine Cervical Interbody Fusion System (K091088)

Device Description:

The DISCOVERY is a cervical interbertebral body fusion device consisting of teeth on the inferior and superior surfaces to prevent back out and migration. The profile of the device is rectangular with a hollow core for bone graft to promote bone integration and fusion between the endplates. The device is available in various heights accommodate variability among patients and is manufactured from PEEK Optima® LT1 per ASTM F2026 and includes tantalum markers per ASTM F560.

Indications for Use:

The DISCOVERY is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with the degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and autograft to facilitate fusion and is to be implanted via an open, anterior approach.

Substantial Equivalence Information:

The design features, material, and indications for use of the DISCOVERY device are substantially equivalent to the predicate device listed above. The safety and effectiveness is

adequately supported by the substantial equivalence, material information, and analysis data provided within this Premarket Notification.

Summary of Non-Clinical Test:

The following mechanical testing was performed per ASTM F2077 and F2267 to demonstrate substantial equivalence of the subject device to the predicate device: Static Compression, Dynamic Compression, Static Torsion, Dynamic Torsion, Subsidence, and Expulsion. The device functioned as intended and the performance results show that the DISCOVERY is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Intuitive Spine, LLC
% Thogus Products Company / RP+M
Ms. Jennifer Palinchik
33490 Pin Oak Parkway
Avon Lake, Ohio 44012

SEP 12 2011

Re: K111484
Trade/Device Name: DISCOVERY Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: September 27, 2011
Received: September 27, 2011

Dear Ms. Palinchik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111484

Device Name: DISCOVERY

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111484