510(k) SUMMARY

CLARIANCE's Idys™ C

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: November 12, 2013

Name of Device and Name/Address of Sponsor

CLARIANCE - Idys™ C

Common or Usual Name

Cervical Intervertebral Body Fusion Device

Classification Name

888.3080 - Intervertebral body fusion

Product Code

ODP

Predicate Devices

Medtronic Sofamor Danek, Inc.'s CORNERSTONE® PSR Spinal System (K100214)

Medicrea Technologies's IMPIX-C Cervical Interbody Device (K072226)

Intended Use / Indications for Use

The Idys™ C device is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The Idys™ C device is to be used with supplemental fixation. The Idys™ C device is also required to be used with autograft and is to be implanted via an open, anterior approach.

Technological Characteristics

The Idys™ C consists of medical grade INVIBIO PEEK OPTIMA LT1 cervical cages of various widths and heights, which can be inserted between two cervical or cervico-thoracic vertebral bodies to give support during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

Performance Data

Performance testing was conducted per ASTM F2077 and ASTM F2267. Specifically, CLARIANCE performed static and dynamic axial compression testing, static and dynamic compression shear testing, subsidence testing, expulsion testing, and wear testing. The results of these studies were determined to be substantially equivalent to legally marketed devices.

Substantial Equivalence

The Idys™ C device is as safe and effective as the Medtronic Sofamor Danek, Inc.'s CORNERSTONE® PSR Spinal System (K100214) and Medicrea Technologies's IMPIX-C Cervical Interbody Device (K072226). The Idys™ C device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Idys™ C device and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Idys™ C device is as safe and effective as the predicate devices. Thus, the Idys™ C device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 13, 2013

Clariance
% Ms. Janice M. Hogan
Partner
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K130853
Trade/Device Name: Idys™ C
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: October 8, 2013
Received: October 8, 2013

Dear Ms. Hogan:

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ronald P. Jean -S for

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K130853

Device Name: Idys™ C

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices