K140992

510(k) Summary

JUN 16 2014

ArthroCare® Corporation

NasaStent™

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name:	ArthroCare Corporation
Address	7000 West William Cannon Drive Austin, TX 78735
Contact Person:	Shannon Scott Sr. Manager, Regulatory Affairs Phone: 512-358-5771 Fax: 512-895-1489
Date Prepared:	April 15, 2014

Device Name

Proprietary Name:	ArthroCare® NasaStent™ CMC Nasal Dressing
Common Name:	NasaStent
Classification Name:	Intranasal splint
Device Class:	Class I
Product Code:	LYA
CFR Section:	21 CFR 874.4780

Predicate Devices

CogENT Nasal/Epistaxis Pack	K113585 (April 25, 2012)
Polyganics NasoPore® Nasal Dressing, Model NDOX-YYY/ZZ	K052099 (November 21, 2005)
Hemostasis NexPak Intranasal Splint	Class I, Exempt

Description

NasaStent is a dissolvable polysaccharide intranasal splint made from plant-based CarboxyMethyl Cellulose (CMC). As it absorbs nasal fluids, it turns into a hydrocolloidal gel that naturally drains from the nasal cavity within several days.

Intended Use/Indications For Use

The ArthroCare NasaStent is intended to minimize bleeding and edema and to prevent adhesions between the septum and the nasal cavity. It is placed in the nasal cavity after surgery or trauma. NasaStent is constructed from absorbent CarboxyMethyl Cellulose (CMC) material.

Summary of the technological characteristics of the device compared to the predicate device

NasaStent shares the same indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices for use as a space-occupying stent/packing for nasal/sinus use. Additionally, comparative performance test data demonstrated adequate device performance.

Performance Data – Summary of Non-Clinical Testing

The ArthroCare NasaStent was evaluated under a number of bench studies to assure safety, efficacy, conformance to design specifications and equivalence to the predicate devices. The following tests were conducted:

- Biocompatibility testing according to ISO 10993-1
- Packaging validation
- Equivalency testing with respect to resiliency, hygroscopic characteristics and form retention

No clinical tests were necessary.

Summary

All testing conducted demonstrates that the ArthroCare NasaStent performs as intended when used in accordance with its labeling. NasaStent is substantially equivalent to the predicate CogENT, NexPak, and Nasopore nasal splints in terms of design, principle of operation, and indications for use and raises no new questions of safety or effectiveness.

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

June 16, 2014

ArthroCare Corporation
Mr. Mitchell Dhority
Vice President, Regulatory Affairs
7000 West William Cannon Drive
Austin, TX 78735

Re: K140992
Trade/Device Name: ArthroCare® NasaStent™ CMC Nasal Dressing
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal splint
Regulatory Class: Class I
Product Code: LYA
Dated: April 15, 2014
Received: April 17, 2014

Dear Mr. Dhority:

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140992

Device Name
ArthroCare® NasaStent™

Indications for Use *(Describe)*
The ArthroCare NasaStent is intended to minimize bleeding and edema and to prevent adhesions between the septum and the nasal cavity. It is placed in the nasal cavity after surgery or trauma. NasaStent is constructed from absorbent CarboxyMethyl Cellulose (CMC) material.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

sunny.park@fda.hhs.gov
2014.06.12 20:33:42 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."