K131709

## 510(k) SUMMARY

***Sinus Dilation System with Cannulated Instrument***

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| **Sponsor**: | ArthroCare Corporation<br>12672 Silicon Drive, Suite 150<br>San Antonio, Texas 78249 USA<br>Telephone: 1-877-300-5010<br>Fax: 1-210-298-6399<br>Contact Person: Gabriele G. Niederauer, Ph.D. |
| **Date Prepared:** | September 17, 2013 |
| **Trade Name**: | ***Sinus Dilation System with Cannulated Instrument*** |
| **Product Code and Device Classification Name**: | LRC<br>Sinus Dilation System (21 C.F.R. § 874.4420) |
| **Classification**:<br>**Predicate Device(s)**: | Class I (exempt from 510(k) requirements)<br>ENTrigue Surgical, Inc. ENTrigue® Sinus Dilation System [K121351] |
| **Purpose of the Special 510(k) notice:** | The ***Sinus Dilation System with Cannulated Instrument*** is a modification to ENTrigue® Sinus Dilation System. |
| **Intended Use:** | The ***Sinus Dilation System with Cannulated Instrument*** is intended for use in surgical procedures to access, examine or treat the nasal and paranasal tissues leading to ostia. |
| **Indications for Use:** | The ***Sinus Dilation System with Cannulated Instrument*** is indicated to access and treat the frontal recesses, sphenoid sinus ostia, and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach. |
| **Technological Characteristics**: | The ***Sinus Dilation System with Cannulated Instrument*** consists of a disposable balloon which is mounted on a reusable cannulated delivery instrument to allow for dilation of sinus ostia in the paranasal cavity under endoscopic guidance. The Sinus Balloon components include a balloon sleeve to slide over the tip of the delivery instrument, a connecting collar to latch the balloon sleeve to the delivery instrument, and an inflation line to connect to the balloon inflation device. The features of this device enable a physician to guide the device |

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to the sinus ostium using endoscopic visualization. The instrument cannulation provides a working channel for suction, irrigation, etc.

The Sinus Balloon Dilation Balloon and inflation device are individually packaged and provided sterile for single use only. The cannulated delivery instrument is a reusable instrument which must be sterilized prior to use following the recommended and validated cleaning and sterilizing procedures.

**Performance Data:**

Bench testing was conducted to validate that the instrument design met user requirements and test results confirmed that the ***Sinus Dilation System with Cannulated Instrument*** is substantially equivalent to the legally marketed predicate device the *ENTrigue*® Sinus Dilation System. Instrument testing included fatigue life, human factors verification, ability to articulate and lock, cleaning and sterilization validations. In all instances, the ***Sinus Dilation System with Cannulated Instrument*** functioned as intended and the results observed were as expected.

**Substantial Equivalence:**

The ***Sinus Dilation System with Cannulated Instrument*** has the same intended use and similar indications, principles of operation, and technological characteristics as *ENTrigue*® Sinus Dilation System. The minor difference in handle design and cannulation of the reusable delivery instrument does not alter the fundamental scientific technology. Verification and validation testing confirms that the modifications do not raise any new risks. Thus, the ***Sinus Dilation System with Cannulated Instrument*** is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 4, 2013

ArthroCare, Inc.
% Gabrielle G. Niederauer, Ph.D.
Senior Director, R & D
7000 W. William Cannon Dr., Bldg. 1
Austin, TX 78735

Re: K131709
Trade/Device Name: Sinus dilation system with cannulated instrument
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, and Throat manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: September 5, 2013
Received: September 6, 2013

Dear Dr. Niederauer:

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,

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

**Indications for Use Statement**

510(k) Number (if known): K131709

Device Name: ***Sinus Dilation System with Cannulated Instrument***

**Intended Use:**

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| Prescription Use ___X___<br>(Per 21 C.F.R. 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(Per 21 C.F.R. 807 Subpart C) |

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Concurrence of Center for Devices and Radiological Health (CDRH)

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