5. 510(k) Summary K092401

NOV 17 2009

Submitter's name:	Sinexus, Inc.
Address:	1049 Elwell Court Palo Alto, CA, 94303
Phone Number:	650-641-2115
Fax Number:	650-641-2065
Contact Person:	Amy Conuel, Director, Regulatory Affairs
Date Prepared:	November 3, 2009
Trade Name:	Sinus Stent
Regulation:	21CFR 874.4780
Product Code:	LYA
Product Classification:	I
Predicate Device:	Sinexus Sinus Stent (K062628) and SyntheMed SinuShield (K082276) AdvaCoat Sinus Gel and Stent (K070496) Nasopore Nasal Dressing (K052099) LactoSorb Ethmoid Stent (K002131)
Device Description:	The Gen 2 Sinexus Sinus Stent is a bioabsorbable stent designed to be placed in the ethmoid sinus to maintain patency of the sinus after surgery.
Intended Use:	The Gen 2 Sinexus Sinus Stent is intended for use in adult patients following sinus surgery to maintain patency of the ethmoid sinus by separating mucosal tissues, providing stabilization of the middle turbinate and preventing obstruction by adhesions between healing and/or inflamed mucosal surfaces.
Rationale for Substantial Equivalence / Comparison to Predicate:	The intended use, technological characteristics and materials of the Sinexus Sinus Stent Gen 2 are substantially equivalent to the predicate devices. The performance testing demonstrates that the Sinexus Sinus Stent Gen 2 is safe and effective for its intended use. The information provided in the 510(k) support that the Sinexus Sinus Stent Gen 2 device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Intersect ENT, Inc.
% Ms. Amy Conuel
Director of Regulatory Affairs
1049 Elwell Court
Palo Alto, CA 94303

NOV 17 2009

Re: K092401
Trade/Device Name: Sinexus Sinus Stent Gen 2
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal splint
Regulatory Class: Class I
Product Code: LYA
Dated: October 5, 2009
Received: October 7, 2009

Dear Ms. Conuel:

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.

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K092401

Device Name: Sinexus Sinus Stent Gen 2

Indications For Use:

The Sinexus Sinus Stent Gen 2 is intended for use in adult patients following sinus surgery to maintain patency of the sinus by separating mucosal tissues, providing stabilization of the middle turbinate and preventing obstruction by adhesions between healing and/or inflamed mucosal surfaces.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K092401