8 Premarket Notification 510(k) Summary

DEC 9 2013

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

510(k) Number: K133016

Applicant Information:

Date Prepared: December 6, 2013

Name:	SinuSys Corporation
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Contact Person:	Michael A Daniel, Consultant
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Device Information:

Device Trade Name:	Vent-Os™ Sinus Dilation System
Common Name:	Instrument, ENT Manual Surgical
Classification Name(s):	Ear, nose, and throat manual surgical instrument.
Product Code/ Regulation:	LRC / 874.4420
Classification:	Class I, Exempt

Predicate Devices:

Relieva Spin Sinus Dilation System (K111875)

XprESS Multi-Sinus Dilation Tool (K121943)

ENTrigue / Ventera (K121351)

Device Description:

The Vent-Os™ Sinus Dilation System is an osmotically driven device that dilates maxillary sinus ostia and associated spaces. The Vent-Os™ Sinus Dilation System is comprised of a Dilation Device preloaded on a Placement Instrument. The Placement Instrument accesses the target site through the nasal passageway and delivers the Dilation Device. The Vent-Os™ Sinus Dilation Device then expands and remodels the target tissues and then is removed.

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Indications for Use:

The Vent-Os™ Sinus Dilation System is an instrument intended to provide a means to access the sinus space and to dilate the maxillary sinus ostia and associated spaces in adults for diagnostic and therapeutic procedures.

Comparison to Predicate Devices:

The Vent-Os™ Sinus Dilation System has the same intended use and similar indication, mechanism of action and procedural outcomes as the Relieva Spin Sinus Dilation System, the ENTrigue Ventera dilation device and the XprESS Multi-Sinus Dilation Tool (the predicate devices). The SinuSys Dilation System dilates maxillary sinus ostia and associated spaces via pressure applied circumferentially in a substantially equivalent manner to the predicate devices. The technological differences between the Vent-Os™ Sinus Dilation System and its predicates do not raise new questions of safety or efficacy. Performance data demonstrates substantially equivalence in terms of safety and effectiveness to the predicate devices.

Performance Testing:

Biocompatibility in compliance with EN ISO 10993 requirements was completed. This biocompatibility testing included:

Item #	Test	Standard Reference	Results
1	Cytotoxicity (MEM Elution)	ISO 10993-5:2009	Non-cytotoxic
2	Sensitization-Maximization	ISO 10993-10: 2010	Non-sensitizing
3	Intracutaneous Reactivity	ISO 10993-10: 2010	Non-irritating

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In Vitro bench evaluation including performance testing was completed. This performance testing included the following evaluations:

Attribute Tested	Pass/Fail
Device weight	Passed
Placement System Working Length Profile	Passed
Placement System Working Length	Passed
Crossing Profile	Passed
Deployment Force	Passed
Dilation Device Diameter @ 1 hour	Passed
Dilation Device Working Length @ 1 hour	Passed
Dilation Device Integrity	Passed
Bond Strength	Passed
Proximal Anchoring Force	Passed

Transportation, sterilization, and shelf-life testing was completed. Sterilization validation was performed in compliance with all requirements of ANSI/AAMI/ISO 11137-2: Sterilization of Health Care Products – Radiation. Transportation and packaging validation included the following:

Attribute Tested	Pass/Fail
Transit Testing	Passed
Sterile Barrier Integrity (Bubble Test)	Passed
Packaging & System Visual Inspection	Passed
Pouch Seal Testing	Passed

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Animal studies confirming safe placement and dilation were conducted. Four (4) Dilation Devices were deployed into four (4) separate sheep maxillary sinuses (MSO).

Cadaver testing was completed by multiple users to validate usability. This cadaver evaluation included use of two (2) adult cadaveric head specimens with the device placed four (4) times into each target site. Investigators confirmed successful endoscopic delivery and placement of the device.

Finally, clinical trials to demonstrate safety and effectiveness were performed by SinuSys Corporation to demonstrate substantial equivalence of the Vent-Os™ Sinus Dilation System to the predicate devices cited. A prospective, non-randomized, single arm, open label, study was conducted at five (5) clinical sites with five (5) investigators. A total of 34 patients and 57 maxillary ostia were treated. Results were comparable to the literature control as summarized in the following table:

	SinuSys Study		Bolger Study[1]	
Analysis	Per Protocol	95% CI*	Per Protocol	95% CI*
	Acute		1 week	
N	57		142	
Patent	54 (95%)	85.6% - 98.2%	106 (75%)	66.9% - 81.1%
Non-Patent	0		0	
Indeterminate	3 (5%)	1.8% - 14.4%	36 (25%)	18.9% - 33.1%
	3 Months		3 Months	
N	55		116	
Patent	51 (93%)	82.7% - 97.1%	98 (84%)	76.8% - 90.0%
Non-Patent	0		3 (3%)	
Indeterminate	4 (7%)	2.9% - 17.3%	15 (13%)	8.0% - 20.2%

*Wilson score confidence intervals

[1]Bolger W et al. Safety and outcomes of balloon catheter sinusotomy: a multicenter 24-week analysis in 115 patients. Otolaryngol Head and Neck Surg 2001, 137: 10-20.

Summary:

Based upon the device description and test data provided in this submission the Vent-Os™ Sinus Dilation System is substantially equivalent to the predicate devices cited.

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

December 9, 2013

SinuSys Corporation
c/o Mr. Michael A. Daniel
Regulatory Consultant
8 Snowberry Court
Orinda, CA 94563

Re: K133016
Trade/Device Name: Vent-Os™ Sinus Dilation System
Regulation Number: 21 CFR 874.4420
Regulation Name: ENT Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: November 24, 2013
Received: November 26, 2013

Dear Mr. Daniel:

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" (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,

Denise L. Hampton -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

510(k) Number (if known): K133016

Device Name: Vent-Os™ Sinus Dilation System

Indications For Use:
The Vent-Os™ Sinus Dilation System is an instrument intended to provide a means to access the sinus space and to dilate the maxillary sinus ostia and associated spaces in adults for diagnostic and therapeutic procedures.

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

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