7DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 29, 2016

SinuSys Corporation
Mr. Lloyd Griese
Vice President, Quality and Regulatory
2468 Embarcadero Way
Palo Alto, CA 94303

Re: K160770
Trade/Device Name: Vent-Os® Sinus Dilation Family
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, And Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: May 31, 2016
Received: June 1, 2016

Dear Mr. Griese:

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" (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 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)*
K160770

Device Name
Vent-Os Sinus Dilation Family

Indications for Use *(Describe)*
SinuSys Vent-Os® Sinus Dilation family is intended to provide a means to access the sinus space and to dilate sinus ostia and associated spaces in adults for diagnostic and therapeutic procedures.

- The Vent-Os Maxillary Dilation System is indicated for dilation of Maxillary sinus and associated spaces.
- The Vent-Os Frontal Dilation System is indicated for dilation of the Frontal recess and associated spaces.
- The Vent-Os Sphenoid Dilation System is indicated for dilation of Sphenoid sinus and associated spaces.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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8 Premarket Notification 510(k) Summary

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: ___K160770_____

Applicant Information:

Date Prepared:	June 25, 2016
Name:	SinuSys Corporation
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Back-up Contact Person:	Michael A. Daniel, Daniel & Daniel Consulting, LLC
Phone Number (Mobile):	415-407-0223
Email:	madaniel@clinregconsult.com

Device Information:

Device Trade Name:	Vent-Os® Sinus Dilation Family
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 Device:

XprESS Multi-Sinus Dilation Tool (K121943)

Reference Devices:

Vent-Os® Sinus Dilation System (K133016)

Relieva Spin Sinus Dilation System (K111875)

Premarket Notification 510(k) Summary - Continued

Device Description:

The Vent-Os® Sinus Dilation family comprises a family of osmotically driven devices that access and dilate the sinus ostia and spaces associated with the paranasal sinus cavities. Each member of the Vent-Os® Sinus Dilation family is a system that includes 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.

Indications for Use:

SinuSys Vent-Os® Sinus Dilation family is intended to provide a means to access the sinus space and to dilate sinus ostia and associated spaces in adults for diagnostic and therapeutic procedures.

- The Vent-Os Maxillary Dilation System is indicated for dilation of Maxillary sinus and associated spaces.
- The Vent-Os Frontal Dilation System is indicated for dilation of the Frontal recess and associated spaces.
- The Vent-Os Sphenoid Dilation System is indicated for dilation of Sphenoid sinus and associated spaces.

Comparison to Predicate Device:

The Vent-Os® Sinus Dilation family has the same intended use and similar indication, mechanism of action, and procedural outcomes as the XprESS Multi-Sinus Dilation Tool (the predicate device). The Vent-Os® Sinus Dilation family also shares similar technological features and mechanism of action with the cleared Vent-Os Sinus Dilation System (for the maxillary sinus). The Vent-Os Sinus Dilation family dilates sinus ostia and spaces associated with paranasal sinus cavities via pressure applied radially in a substantially equivalent manner to the predicate device. The technological differences between the Vent-Os® Sinus Dilation family and its predicate do not raise new questions of safety or effectiveness. Performance data demonstrate substantial equivalence in terms of safety and effectiveness to the predicate device.

Performance Testing

Biocompatibility in conformance with applicable requirements of ISO 10993 was completed. This 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

Premarket Notification 510(k) Summary - Continued

Bench testing to evaluate conformance with required device attributes and performance was completed. This 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

Transportation, sterilization, and shelf-life testing was completed to evaluate conformance with required attributes and performance. Sterilization validation was performed in conformance with all applicable requirements of ANSI/AAMI/ISO 11137-2: Sterilization of Health Care Products – Radiation. Results demonstrate achievement of a sterility assurance level (SAL) of 10^{-6}.

Transportation and packaging validation included the following:

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

Premarket Notification 510(k) Summary - Continued

Cadaver testing was completed by multiple physician users to validate usability. The cadaver evaluations included use of cadaveric head specimens with the devices placed multiple times into each targeted sinus site. Evaluators confirmed successful delivery and placement of the devices to the targeted sinus.

A clinical trial was also performed by SinuSys Corporation to demonstrate the substantial equivalence, in terms of the safety and effectiveness, of the Vent-Os® Sinus Dilation family to the predicate device cited. A multi-center, prospective, single arm, non-randomized trial was conducted at three (3) clinical sites with three (3) investigators to evaluate basic usability and confirm safety and effectiveness of the Vent-Os® Sinus Dilation family to dilate the frontal recess and sphenoid sinus ostia in patients with chronic rhinosinusitis. Use of the Vent-Os® Sinus Dilation family for maxillary sinus ostia dilation was the subject of cleared pre-market notification K133016. A total of 30 patients were enrolled and treated in the study. In the 30 treated subjects, 33/33 frontal recesses and 15/15 sphenoid sinus ostia were successfully treated. Clinical trial results achieved for frontal recess and sphenoid sinus ostia were comparable to the literature control as summarized in the following table:

Comparison to Literature Control

	SinuSys Study		Bolger Study*	
Analysis	Per Protocol	95% CI**	Per Protocol	95% CI**
Frontal Recess				
	Acute		1 week	
N	33		124	
Patent	33 (100%)	92.4% - 100%	85 (69%)	59.9% - 76.1%
Non-Patent	0	-	7 (6%)	2.8% - 11.2%
Indeterminate	0	-	32 (26%)	18.9% - 34.2%
	3 Months		3 Months	
N	30		98	
Patent	28 (93%)	78.7% - 98.2%	82 (84%)	75.1% - 89.7%
Non-Patent	0	-	3 (3%)	1.1% - 8.6%
Indeterminate	2 (7%)	1.9% - 21.3%	13 (13%)	7.9% - 21.4%
Sphenoid Sinus Ostium				
	Acute		1 week	
N	15		75	

Patent	13 (87%)	62.1% - 96.3%	41 (55%)	43.5 – 65.4%
Non-Patent	0	-	0	-
Indeterminate	2 (13%)	3.7% - 37.9%	34 (45%)	34.6% - 56.6%
	3 Months		3 Months	
N	15		54	
Patent	10 (67%)	41.7% - 84.8%	32 (59%)	46.0% - 71.3%
Non-Patent	0	-	0	-
Indeterminate	5 (33%)	15.2% - 58.3%	22 (41%)	28.7% - 54.0%

* Literature control Bolger, et al. Safety and outcomes of balloon catheter sinusotomy: A multicenter 24-week analysis in 115 patients. Otolaryngol Head and Neck Surg 2007, 137: 10-20.

**Wilson score confidence intervals

Clinical trial results substantiated the Vent-Os® devices perform safely, effectively, and in a manner substantially equivalent to cited predicate and reference devices.

Summary:

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