October 15, 2020

Stryker ENT
Bruce Backlund
Principal Regulatory Affairs Specialist
3600 Holly Lane North, Suite 40
Plymouth, Minnesota 55447

Re: K201398
Trade/Device Name: SINUSPRIME Dilation System
Regulation Number: 21 CFR 874.4180
Regulation Name: Eustachian Tube Balloon Dilation System
Regulatory Class: Class II
Product Code: PNZ, LRC
Dated: September 14, 2020
Received: September 16, 2020

Dear Bruce Backlund:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shu-Chen Peng

for Malvina Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201398

Device Name
SINUSPRIME Dilation System

Indications for Use *(Describe)*

Use a single dilation device by transnasal approach to access and treat an individual anatomical location as follows:

• Remodel by balloon displacement the adjacent bone and paranasal sinus structures in the Maxillary ostia/ethmoid infundibula in patients 2 years and older;
• Remodel by balloon displacement the adjacent bone and paranasal sinus structures in the Frontal ostia/recesses in patients 12 years and older; may be used with LED Light fiber to locate, illuminate within and, transilluminate across nasal and sinus structures;
• Remodel by balloon displacement the adjacent bone and paranasal sinus structures in the Sphenoid sinus ostia in patients 12 years and older;
• Dilation of the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in patients 18 years and older.

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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510(K) SUMMARY

Date Prepared: May 27, 2020

Submitter Information:
Stryker ENT
3600 Holly Lane North, Suite 40
Plymouth, MN 55447

Establishment Registration: 3006345872

Contact Information:
Bruce Backlund
Principal Regulatory Affairs Specialist
(763) 762-5902
bruce.backlund@stryker.com

Device Information:

Trade Name: SINUSPRIME Dilation System
Common Name: Balloon Sinus Dilation System
Classification Name: ENT Manual Surgical Instrument
Eustachian Tube Balloon Dilation Device

Product Code: LRC
PNZ

Regulation Number: Class I, 21 CFR 874.4420
Class II 21 CFR 874.4180

Predicate Devices: K163509 XprESS ENT Dilation System
K152435 LED Light Fiber

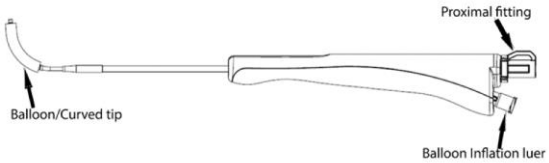
Device Description:

The SINUSPRIME Dilation System is intended to remodel or recreate the sinus outflow tract and dilate the Eustachian tube by transnasal balloon dilation. Each packaged SINUSPRIME System includes a balloon device configured for a specific anatomy (frontal, sphenoid, maxillary, or Eustachian tube (ET) configuration) and an inflation device.

SINUSPRIME Dilation System Configurations and Included Accessories						
Configuration	Balloon Device	Balloon Size	Accessories			
			Inflation Syringe	Extension Line	LED Light Fiber	IGS Adapter
Frontal	X (Frontal)	6x20	X	X		X
Frontal w/ LED	X (Frontal)	6x20	X	X	X	X
Sphenoid	X (Sphenoid)	6x20	X	X		X

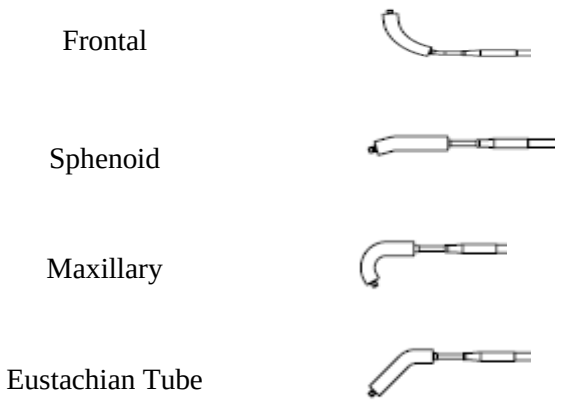
Maxillary	X (Maxillary)	6x8	X	X		
Eustachian Tube (ET)	X (ET)	6x20	X	X		

The SINUSPRIME Dilation System combines features of an ostium seeker with the tissue expansion effect of balloon dilation. The SINUSPRIME Dilation System is provided sterile and for single use only. The familiar features of this device enable a physician to track the device into the sinuses and Eustachian tubes using endoscopic visualization.

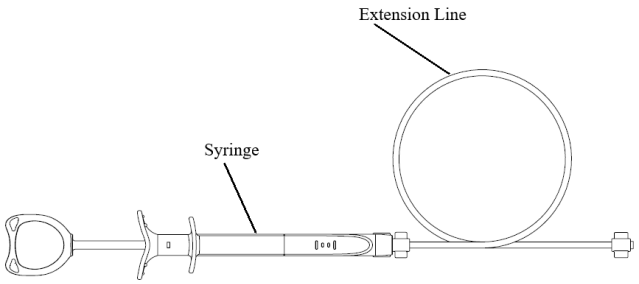


SINUSPRIME Dilation Device (shown with balloon protector on tip)

SINUSPRIME Dilation System includes a balloon device configured for a specific anatomy (frontal, sphenoid, maxillary, or Eustachian tube (ET) configuration) and an inflation device with extension line.

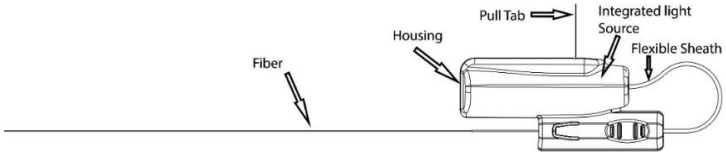


SINUSPRIME Dilation Device tip configurations (shown with balloon protector on tip)



Inflation Device with Extension Line

The SINUSPRIME LED Light Fiber consists of a flexible illumination fiber that allow physicians to locate, illuminate within, and trans-illuminate across nasal and sinus structures. The SINUSPRIME LED Light Fiber is optional and available packaged and pre-loaded only on the SINUSPRIME Frontal with LED model.



SINUSPRIME LED Light Fiber

Indications for Use:
Use a single dilation device by transnasal approach to access and treat an individual anatomical location as follows:

- Remodel by balloon displacement the adjacent bone and paranasal sinus structures in the Maxillary ostia/ethmoid infundibula in patients 2 years and older;
- Remodel by balloon displacement the adjacent bone and paranasal sinus structures in the Frontal ostia/recesses in patients 12 years and older; may be used with LED Light fiber to locate, illuminate within and, transilluminate across nasal and sinus structures;
- Remodel by balloon displacement the adjacent bone and paranasal sinus structures in the Sphenoid sinus ostia in patients 12 years and older;
- Dilation of the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in patients 18 years and older.

Contraindications:
None known.

Technological Characteristics:
The technological characteristics of the subject device are very similar to the predicate devices [K163509 and K152435], including: principle of operation, design, function, materials, biocompatibility and sterility.

Both the subject device and predicate balloon device [K163509] are configured or chosen for a specific anatomy (frontal, sphenoid, maxillary, or Eustachian tube (ET) configuration) to facilitate dilation procedures and include an inflation device and an option to include a LED Light Fiber [predicate device K152435] that emits light from the distal end. The subject device has a single stainless steel hypotube that remains rigid and cannot be bent. The tip configuration for the subject rigid devices are therefore specific to the desired anatomical site (frontal, sphenoid, maxillary, or Eustachian tube (ET)) and packaged accordingly. The balloon predicate device [K163509] has two stainless steel hypotubes that have been annealed to allow bending with the included bending tool such that a single device can be used in various anatomical configurations (frontal, sphenoid, maxillary, or Eustachian tube (ET)). Both the subject device (frontal and sphenoid configurations) and the predicate device [K163509] accommodate the use of guidewires if desired. Unlike the predicate device [K163509], the subject device is not designed for optional suction or irrigation.

Substantial Equivalence:
The indications for use and intended use of the subject device are the same as the predicate devices [K163509 and K152435]. The technological characteristics of the subject device are similar to the predicate devices [K163509 and K152435], including: principle of operation, design, function, materials, biocompatibility, and sterility.

Performance Data:
Performance testing involved biocompatibility, design verification (dimensional, functional, strength, HFE/UE verification testing), packaging, shelf life and design validation with physicians (HFE/UE). Performance testing showed that the device meets design specifications and performs as intended.

Conclusion:
In conclusion, the SINUSPRIME indications for use and technological characteristics are the same as or equivalent to the predicate device. The differences between the subject device and the predicate device (e.g., update to a rigid hypotube that cannot be bent) do not raise different questions of safety or effectiveness and performance testing has been conducted to demonstrate the subject device is substantially equivalent to the predicate devices.