December 15, 2017

STS Medical
% George Hattub
Senior Staff Consultant
Medicsense
291 Hillside Avenue
Somerset, MA 02726

Re: K170913
Trade/Device Name: Composite Removable Sinus Stent System
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal Splint
Regulatory Class: Class I
Product Code: LYA
Dated: November 14, 2017
Received: November 20, 2017

Dear George Hattub:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

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)*

K170913

Device Name

Composite Removable Sinus Stent System

Indications for Use *(Describe)*

Intended Use

The Composite Removable Sinus Stent is intended for use in adult patients following ethmoid sinus surgery, to maintain patency and reduce the need of post-operative intervention or revision surgery. The composite stent is intended to be left inside the ethmoid sinus cavity for up to 28 days. The composite sinus stent provides steady support of nasal walls against swelling mucosa, middle turbinate stabilization and prevents obstruction by adhesions. The stent can be removed at any time within 28 days by cooling and self-crimping.

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.

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STS Medical

Expert Building 2nd floor, 37 Amal Street,
Kyriat Arie, Petah Tikva, 4951337, Israel

Tel: 972-54-7387188
Fax: 972-72-260-7200

510(k) SUMMARY: K170913

Submitter's Name, address, telephone number, a contact person and date the summary was prepared:

Submitter's Name:	STS Medical
Submitter's Address:	Expert Building 2nd floor, 37 Amal Street, Kyriat Arie, Petah Tikva, 4951337, Israel
Submitter's Telephone:	972-54-7387188
Submitter's Contact:	Lena Shlossberg M.Sc. QA / RA manager Tel: +972-52-6826962 E-mail: lena@ststent.com
Date of Submission	March 22, 2017

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Proprietary Name:	Composite Removable Sinus Stent System
Common or Usual Name:	Sinus Stent System
Classification Name:	Ear, Nose, and Throat Surgical Device, Intranasal splint
Regulatory Class	I
Product code:	LYA
Predicate Device:	K092401 Sinus Stent, product code LYA
	The intended use of the device is similar to the predicate. The basic features and principle of operations of the device are similar to the predicate device. Any minor differences do not affect safety and effectiveness of the device when used as labeled.

Expert Building 2nd floor, 37 Amal Street,
Kyriat Arie, Petah Tikva, 4951337, Israel
Tel: 972-54-7387188
Fax: 972-72-260-7200

Reference Device: K120280 Relieva Seeker Balloon Sinuplasty System, product code LRC.
This reference device comprises the feature of balloon dilatation inside intranasal structures, therefore helps to address the question of safety and effectiveness that is raised by the Delivery System of the subject device.

Device Description

The subject device is supplied sterile for single use.
The composite removable sinus stent provides sinus wall support following functional endoscopic sinus surgery. A delivery system is provided to insert the implant. The system contains the following components:

Stent

The stent is balloon expandable and composed of an outer polyurethane and inner Nitinol alloy bodies. The stent is designed to accommodate the size and variability of the post-surgical ethmoid cavity anatomy. Once expanded the stent is designed to support the walls of ethmoid cavity, in order to prevent adhesions and middle turbinate lateralization into the septum. Stent can be removed within 4 weeks by cooling and self-crimping

Delivery System

The delivery system is designed to insert, position and deploy the stent, following functional endoscopic sinus surgery, guided by endoscopic direct vision. The delivery system consists of a water filled syringe connected to high compliance low pressure balloon via rigid shaft. The balloon is supplemented with color marker.

Intended Use

The Composite Removable Sinus Stent is intended for use following ethmoid sinus surgery, to prevent adhesions and middle turbinate lateralization into the septum. The composite stent is intended to be left inside the ethmoid sinus cavity for up to 28 days. The composite sinus stent provides steady support of nasal walls against swelling mucosa, middle turbinate stabilization and prevents obstruction by adhesions. The stent can be removed at any time within 28 days by cooling and self-crimping.

Technological Characteristics
Provided below is a table summarizing and comparing the technological characteristics of Composite Removable Sinus Stent System and the predicate device.

Expert Building 2nd floor, 37 Amal Street,
Kyriat Arie, Petah Tikva, 4951337, Israel
Tel: 972-54-7387188
Fax: 972-72-260-7200

	Predicate Device	Subject Device
Company Name	Sinexus Inc	STS Medical
Code / Class	LYA. Class I	LYA. Class I
Device Name	Sinus Stent	Composite Removable Sinus Stent System
Intended Use	Post-operation separate mucosal tissues and prevent adhesions.	Post-operation separate mucosal tissues and prevent adhesions.
Material / Construction	Absorbable poly-L-lactide-co-glycolide	Nitinol alloy & polymer
Sterility	Radiation	EtO
Bioresorbable	Yes	No
Biocompatibility	ISO 10993- 1	ISO 10993- 1
Method of Action	Mechanical support of the surgically enlarged sinus.	Mechanical support of the surgically enlarged sinus.
Method of Removal	Resorption or aspiration	Cooling induced self-crimp and removal with medical grasper

	Reference Device	Subject Device Delivery System
Company Name	Acclarent Inc.	STS Medical
Code / Class	LRC	LYA. Class I
Device Name	Relieva Seeker Balloon Sinuplasty System	Composite Removable Sinus Stent System
Intended Use	Access and dilate spaces within frontal sinus cavity.	Insert, position and deploy the stent within ethmoid sinus
Material / Construction	Nylon balloon with stainless steel shaft	Nylon/silicone balloon with stainless steel shaft
Sterility	EtO	EtO
Bioresorbable	No	No
Biocompatibility	ISO 10993- 1	ISO 10993- 1
Method of Action	Balloon inflation under endoscopic visualization for dilatation of intranasal structures	Balloon inflation for stent deployment
Method of Removal	Balloon deflation and system retraction	Balloon deflation and system retraction

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Kyriat Arie, Petah Tikva, 4951337, Israel
Tel: 972-54-7387188
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The following technological differences exist between the subject and predicate devices:

- Sinexus Sinus Stent is bioabsorbable device, whether STS Composite Sinus Stent manufactured from non-bioabsorbable, biocompatible materials.
- Sinexus Sinus Stent removed by resorption, whether STS Composite Sinus Stent removed mechanically.

There are no significant differences in the technological characteristics of this device compared to the predicate device which adversely affect safety or effectiveness.

Performance Data

Bench testing

Testing procedures performed under Design Verification Study included the following:

- Composite Stent Integrity
- Composite Stent Dimensional Verification Test
- Composite Stent Functional Test
- Composite Stent Crush Resistance Test
- Composite Stent Radial Strength Test
- Composite Stent Corrosion Resistance Test
- Delivery System Integrity Test
- Delivery System Dimensional Verification Test
- Delivery System Repeat Inflation Test
- Composite Stent System Crossing Profile Verification Test
- Composite Stent System Simulated Use Test

Bench testing met all acceptance criteria of the Design Verification tests and complied with 311001 Composite Removable Stent System Specifications.

Biocompatibility testing

Biocompatibility testing conducted according to "ISO 10993-1 (2009/Cor.1: 2010): Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", " FDA General Program Memorandum #G95-1, Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" demonstrate that Composite Removable Sinus Stent System is biocompatible. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Chemical Characterization

When used as intended, the Composite Sinus Stent is categorized as a surface device in contact with breached or compromised surfaces for prolonged duration (> 24h but < 30 days). Delivery System remains in contact with tissues for 2-3 minutes.

Expert Building 2nd floor, 37 Amal Street,
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Animal Study

In GLP animal study 5 sheep underwent intranasal implantation with Composite Removable Sinus Stent, following erosion of implantation site, designed to simulate tissue condition after functional endoscopic surgery. Total 10 stents were implanted and 10 control sites were created. 3 sheep underwent stent removal after 4 weeks and remained to heal for additional 2 weeks. Thereafter stent and control sites were harvested 6 weeks' post-implantation for histopathological analysis. 2 sheep were sacrificed after 4 weeks' implantation time and stent and thereafter control sites were harvested for histopathological analysis.

Safety and feasibility of the Composite Removable Sinus Stent were evaluated by macroscopic and histological analysis of the tissue from stent implantation sites.

No adverse local tissue adverse effects were observed after 4 weeks' implantation time.

The study demonstrate that Composite Removable Sinus Stent can be safely implanted into nasal meatus for up to 28-day implantation time, similar to the predicate Sinexus Sinus Stent.

Clinical Data

In First in Man Clinical Study 29 stents were successfully implanted and removed from 15 patients. Composite Stent implantation and removal procedures were not associated with any complications or adverse events. Patients' follow-ups have demonstrated that Sinus Stent implantation has not induced any additional inflammatory reaction, to that experienced by the control group patients. In addition the inflammation levels were lower in study group patients and the post-surgical healing was faster in comparison to the standard of care treatment. Study group patients demonstrated lower adhesion and restenosis rate compared to control group patients, at stent removal day and after stent removal (6-12 weeks after FESS). Pain associated with stent removal was lower than pain associated with tampon removal. Study patients have experienced an improvement during stent implantation, while standard of care patients have experienced tampon associated discomfort. The mean difference in SNOT-20 scores before the FESS and 12 weeks after FESS, was higher in study group than in the control group. The discomfort level associated with pre-cooled saline wash was assessed on 11 study group patients on stent removal day. Each patient underwent a randomized wash with pre-cooled / room temperature saline wash in left / right nostril, thus each patient served as a self-control for discomfort level associated with pre-cooled saline, while room temperature saline acted as control treatment.

This demonstrated that the cold saline wash produced negligible discomfort itself and this discomfort may be even less than RT saline wash.

Overall, based on these study results, it can be concluded that the Composite Removable Stent keeps the nasal passage open and promotes post-surgical healing.

Sterilization & Shelf Life

Sterilization of the subject device is performed by ethylene oxide, and was validated according to ISO 11135;2014 and demonstrated a sterility assurance level of 10^{-6}. Ethylene oxide residuals were tested and met ISO 10993-7:2008 requirements. The subject device met

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acceptance criteria of Bacterial Endotoxin Test according to USP 85. The subject device was not tested nor labeled as "non-pyrogenic".

Packaging Shelf life was established in compliance with ISO 11607-1,2, ASTM F1980, ASTM F1929, ASTM F88, ASTM D4332, ASTM D4169, ASTM D999, ASTM D4728 and ASTM D5276.

Summary of Substantial Equivalence

The Composite Removable Sinus Stent System is substantially equivalent to the predicate device Sinus Stent K092401. The reference device Relieva Seeker Balloon Sinuplasty System K120280 helps to address the question of safety and effectiveness of new technological characteristic of intranasal balloon dilatation comprised by the Delivery System of the subject device.

Conclusion

The device meets all the biocompatibility test requirements and is substantially equivalent in design, intended use and technological characteristics to the predicate devices. Therefore, a determination can be made that Composite Removable Sinus Stent System is considered substantially equivalent to the predicate devices.