DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 28, 2016

SPIWay LLC
Ms. Mary Lou Mooney
Regulatory Consultant
1120 Calle Cordillera, #102
San Clemente, CA 92673

Re: K153686
Trade/Device Name: SPIWay Endonasal Access Guide
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal Splint
Regulatory Class: Class I
Product Code: LYA
Dated: December 17, 2015
Received: December 23, 2015

Dear Ms. Mooney:

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,

Kesia Y. Alexander -A

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)*
K153686

Device Name
SPIWay Endonasal Access Guide

Indications for Use *(Describe)*
The SPIWay Endonasal Access Guide is indicated for use in endoscopic sphenoid sinus and transsphenoidal surgery.

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 OF SAFETY AND EFFECTIVENESS

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

1. SUBMITTER INFORMATION

a. Company Name: SPIWay, LLC

b. Company Address: SPIWay, LLC
1120 Calle Cordillera ste 102
San Clemente , CA 92673

c. Telephone: (844)-565-1226
Fax: (814)-295-1226

d. Contact Person: Mary Lou Mooney
Regulatory Consultant

e. Date Summary Prepared: December 16, 2015

2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name: SPIWay Endonasal Access Guide

b. Common Name: Nasal splint

c. Classification Name: Intranasal splint, 874.4780
Product code LYA

3. IDENTIFICATION OF PREDICATE DEVICES

SPIWay Endonasal Access Guide (K132721)

4. DESCRIPTION OF THE DEVICE

The SPIWay Endonasal Access Guide is a sterile, single patient use device placed within the nostril/nasal cavity during endoscopic sphenoid sinus or transsphenoidal surgery to facilitate visualization of the surgical site and smooth manipulation of introduced instruments. It is made of a thermoplastic elastomer.

5. INDICATIONS FOR USE

The SPIWay Endonasal Access Guide is indicated for use in endoscopic sphenoid sinus and transsphenoidal surgery.

6. TECHNOLOGICAL CHARACTERISTICS

The SPIWay Endonasal Access Guide and the predicate SPIWay device are a cylindrically-shaped, flexible thermoplastic elastomer placed within the nasal cavity. Both devices are supplied sterile (gamma radiation). Both devices are placed prior to transnasal surgery and held in position by the proximal flare and conical distal body. The subject device has the same indications for use and same technological characteristics (i.e., principle of operation, basic design, function, basic materials, biocompatibility, packaging and sterilization) as the predicate device.

7. PERFORMANCE DATA

Design verification bench testing was performed for the SPIWay Endonasal Access Guide to demonstrate that physical and functional requirements were met. Design validation cadaver testing was performed for the SPIWay Endonasal Access Guide to demonstrate effectiveness for its intended use. Performance testing showed the device meets design specifications and performed as intended.

8. BIOCOMPATIBILITY

Biocompatibility testing was performed using ISO 10993-Biological Evaluation of Medical Devices. The SPIWay Endonasal Access Guide complies with the biocompatibility requirements for its intended use.

9. CONCLUSION

Through the data and information presented, SPIWay, LLC, considers the SPIWay Endonasal Access Guide substantially equivalent to the predicate device in terms of indications for use, technological characteristics, design and functional performance and that it presents no new concerns about safety or effectiveness.