



February 16, 2018

SPIWay, LLC
Mary Lou Mooney
Regulatory Consultant
3600 Corte Castillo
Carlsbad, CA 92009

Re: K180141
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: January 17, 2018
Received: January 18, 2018

Dear Mary Lou 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.

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,

Srinivas Nandkumar -S

for Malvina 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)

K180141

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.

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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
3600 Corte Castillo
Carlsbad , CA 92009
- c. Telephone: (844)-565-1226
Fax: 614-737-4760
- d. Contact Person: Mary Lou Mooney
Regulatory Consultant
- e. Date Summary Prepared: January 17, 2018

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 (K153686).

4. DESCRIPTION OF THE DEVICE

The SPIWay®Endonasal Access Guide is a temporary working channel sheath for use in endoscopic sphenoid sinus and transsphenoidal surgery. The device consists of a single piece of thermoplastic polymer with a low friction coating, which creates a working channel sheath in the

natural orifice of the nose to facilitate visualization of the surgical site and smooth manipulation of introduced instruments during transnasal endoscopic surgery.

The shape of the SPIWay Endonasal Access Guide contains a flared portion at the proximal end of the device which remains outside the nasal passage and a conical body that sits within the nasal cavity. The flared proximal end and conical body act to anchor the device, preventing migration once inserted and allow simple removal. The device has an elliptical shape, and the major axis of the ellipse is oriented vertically with the nostril.

The device is supplied in several lengths that are selected based upon the surgeon’s needs. It is provided sterile and for single use in a pack of two, one for each nostril. A pair of devices is sealed in a Tyvek pouch and 5 pouches are placed into a labeled carton.

The modifications made to the subject device are summarized below:

- Replaced the hydrophilic coating with a silicone coating.
- Changed the material from a thermoplastic elastomer to a thermoplastic polymer.
- Supply the device in three lengths rather than one length and one aperture size rather than three.

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.

Table 1 – SPIWay Endonasal Access Guide Substantial Equivalence

Characteristic	Predicate Device (SPIWay Endonasal Access Guide, K153686)	Modified Device
Intended Use	To facilitate visualization of the surgical site and smooth manipulation of introduced instruments during transnasal endoscopic surgery	Same

Characteristic	Predicate Device (SPIWay Endonasal Access Guide, K153686)	Modified Device
Indications for Use	For use endoscopic sphenoid sinus and transsphenoidal surgery.	Same
Sterilization Method	Gamma radiation	Same
Packaging	A pair of devices are mounted on a high density polyethylene (HDPE) insert card and placed into a labeled, Tyvek pouch. Pouches are placed into a labeled carton.	Same
Single Use	Yes	Same
Sizes	<u>Length:</u> Nominal total length= 8.8cm; Nominal inf. length =7.5 cm; device trimmable by MD to desired working length <u>Height and width (3 sizes):</u> 9.3 x 4.9mm, 11.2 x 6.5 mm and 13.6 x 9.5mm	<u>Length (3 sizes):</u> Nominal total lengths of 5.6, 6.5 and 7.6 cm; Nominal inf. lengths of 4.0, 5.0 and 6.0 cm <u>Height and width:</u> 12.5 x 8.5 mm
Material	Thermoplastic elastomer with hydrophilic coating	Thermoplastic polymer (PET) with silicone coating
Mechanism of Action	Positioned in nostril to create a working channel sheath in the natural orifice of the nose to facilitate visualization of the surgical site and smooth manipulation of introduced instruments during transnasal endoscopic surgery	Same
Method of insertion into nasal cavity	Forceps	Same
Duration of use	Removed at conclusion of surgical procedure	Same

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 in accordance with ISO 10993-Biological Evaluation of Medical Devices. Specific tests are listed below:

- Cytotoxicity (in accordance with ISO 10993-5:2009)
- Intracutaneous Irritation (in accordance with ISO 10993-10:2010)
- Acute Systemic Toxicity (in accordance with ISO 10993-11:2006)
- Sensitization (in accordance with 10993-10:2010)

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.