October 27, 2021

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

Re: K213153
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: September 27, 2021
Received: September 28, 2021

Dear Mary 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. 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, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213153

Device Name
SPIWay Endonasal Access Guide

Indications for Use *(Describe)*
The SPIWay Endonasal Access Guide is indicated for use in endoscopic transnasal sphenoid sinus and skull base 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

This 510(k) summary 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: Fax:	(844)-565-1226 614-737-4760
d. Contact Person:	Mary Lou Mooney Regulatory Consultant
e. Date Summary Prepared:	October 21, 2021

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 (K180141).

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 transnasal sphenoid sinus and skull base 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 transnasal sphenoid sinus and skull base surgery.

6. TECHNOLOGICAL CHARACTERISTICS

There are no differences in technological characteristics between the subject device and the predicate device.

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

7. PERFORMANCE DATA

Since the subject device is unchanged from the predicate device, repeat design verification and validation testing were not required.

8. BIOCOMPATIBILITY

Since the subject device is unchanged from the predicate device, repeat biocompatibility testing was not required.

9. CONCLUSION

The Indications for Use statement was changed to more accurately describe use of the SPIWay Endonasal Access Guide in current endoscopic transnasal skull base surgical practice. The subject device is identical to the predicate device. The intended use, Instructions for Use and mechanism of action of the subject device are identical to the predicate device. As such, the change in the Indications for Use statement does not affect the substantial equivalence to the predicate device.

Through the 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.