August 30, 2023

Axon Spine Medical System
℅ Tawney Schwarz
Senior Quality & Regulatory Consultant
Quality Solutions and Support, LLC.
7728 Greenbrier Circle
Port Saint Lucie, Florida 34986

Re: K223303
Trade/Device Name: Spinery™ RF Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 2, 2023
Received: August 2, 2023

Dear Tawney Schwarz:

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,

Jesse Muir -S

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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)*
K223303

Device Name
Spinery™ RF Ablation System

Indications for Use *(Describe)*
Spinery™ RF Ablation System is intended for:

- Palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.
- Coagulation and ablation of tissue in bone during surgical procedures including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.

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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K223303

510k Summary

Spinery™ RF Ablation System
by
Axon Spine Medical Systems

Contact Details and Device Name

Submitter:	Axon Spine Medical Systems Piazza Vanvitelli, 5 80127 Napoli NA, Italy Contact Person: Stefano Pasquino Phone: +39 3494463940
Contact:	Tawney Schwarz Senior Quality & Regulatory Consultant Simple Path LLC *(formerly Quality Solutions and Support, LLC)* Phone: 910-515-0918 Email: Tawney@SimplePath.Solutions (former email: tas@qss-llc.com)
Device Trade Name:	Spinery™ RF Ablation System
Common Name:	Electrosurgical cutting and coagulation device and accessories
Classification Number:	21 CFR 878.440
Classification Name:	Electrosurgical, Cutting and Coagulation Device And Accessories
Product Code:	GEI

510k Summary

Spinery™ RF Ablation System
by
Axon Spine Medical Systems

Legally Marketed Predicate Devices

Primary Predicate

Predicate Name - Medtronic OsteoCool RF Ablation System
Predicate Number: K182497

Secondary Predicate

Predicate Name - Stryker OptaBlateTM RF Ablation System
Predicate Number: K221074

Device Description Summary

Spinery™ RF Ablation System is an active medical device, intended for radiofrequency thermal ablation of spine metastatic tumors.

It is a surgically invasive device intended for transient use, as the catheter penetrates percutaneously the human body in the target bone through a surgical incision, aided by other accessories (bone access kit), and remains in the body for the treatment time, estimated in about 20 minutes as a maximum time length.

It is an active therapeutic device because it is intended to provide treatment and pain alleviation of tumoral modifications of the human bone.

It is not intended to be used on the central nervous system.

The Spinery™ RF Ablation System includes the following components:

1. Spinery™ Radiofrequency Generator (REF: SPINERY)
    a. Peristaltic Pump
2. Spinery™ Needles:
    a. Bipolar cooled needle with electrodes length of 7 mm and intra-electrodes length of 4 mm (REF: SP-BI0704)
    b. Bipolar cooled needle with electrodes length of 10 mm and intra-electrodes length of 5 mm (REF: SP-BI1005)
3. Spinery™ Connections
    a. Cooling system connection pipe for double needle approach (REF: SP-CD)

b. Cooling system connection pipe for single needle approach (REF: SP-CS)

4. Manual Infusion System
5. Bone Access Kit
    a. The SP-BI0704 needle has the access kit with code AXONKIT-22
    b. The SP-BI1005 needle has the access kit with code AXONKIT-29

Intended Use/ Indications for Use

The SPINERY™ RF Ablation System is intended for:

- Palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.
- Coagulation and ablation of tissue in bone during surgical procedures including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.

Technological Comparison (SE Table)

	SUBJECT DEVICE	**PRIMARY PREDICATE**	**SECONDARY PREDICATE**	**Identical/ Substantially Equivalent (SE)**
	Spinery™ RF Ablation System	**OsteoCool™ RF Ablation System (K182497)**	**OptaBlate™ RF Ablation System (K221074)**	
Manufacturer	Axon Spine Medical Systems	Medtronic Sofamor Danek USA, Inc	Stryker Corporation	N/A
510(K) #	TBD	K182497	K221074	N/A
Class	II	II	II	Identical
Product Code	GEI, 878.4400	GEI, 878.4400	GEI, 878.4400	Identical
User	Physicians familiar with RF lesion techniques	Physicians familiar with RF lesion techniques	Physicians (IR), Scrub Techs/Nurses, Central Sterile	Identical

Spinery™ RF Ablation System
by
Axon Spine Medical Systems

	SUBJECT DEVICE **Spinery™ RF Ablation System**	PRIMARY PREDICATE **OsteoCool™ RF Ablation System (K182497)**	SECONDARY PREDICATE **OptaBlate™ RF Ablation System (K221074)**	**Identical/ Substantially Equivalent (SE)**
			Techs	
Environment Of Use	Intended for use in hospitals or clinics by specialized medical staff	Intended for use in hospitals or clinics by specialized medical staff	Intended for use in hospitals or clinics by specialized medical staff	Identical
Indications For Use	The Spinery™ RF Ablation System is intended for: • Palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body. • Coagulation and ablation of tissue in bone during surgical procedures including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.	The OsteoCool™ RF Ablation System is intended for: • Palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body. • Coagulation and ablation of tissue during surgical procedures such as palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy. • Ablation of benign bone tumors such as osteoid osteoma.	The intended use of the OptaBlate™ Radiofrequency (RF) Generator System is as follows: •Palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body. • Coagulation and ablation of tissue in bone during surgical procedures including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy. • Ablation of benign bone tumors such as osteoid	SE

Spinery™ RF Ablation System
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Axon Spine Medical Systems

	SUBJECT DEVICE	PRIMARY PREDICATE	SECONDARY PREDICATE	Identical/ Substantially Equivalent (SE)
	Spinery™ RF Ablation System	**OsteoCool™ RF Ablation System (K182497)**	**OptaBlate™ RF Ablation System (K221074)**	
			osteoma.	
Anatomical Site Of Use	Bone	Bone	Bone	Identical
Access Method	Percutaneous	Percutaneous	Percutaneous	Identical
Energy Type	Radiofrequency Energy	Radiofrequency Energy	Radiofrequency Energy	Identical
Principle Of Operation	Operator controlled; RF delivered from compatible RF generator via connector cable	Operator controlled; RF delivered from compatible RF generator via connector cable	Operator controlled; RF delivered from compatible RF generator	Identical
Mechanism Of Action	Cellular necrosis through thermal coagulation	Cellular necrosis through thermal coagulation	Cellular necrosis through thermal coagulation	Identical
Rate Of Temperature Rise In Sample Tissues	Controlled by RF generator energy output mechanism	Controlled by RF generator energy output mechanism	Controlled by RF Generator	Identical
Feedback Mechanism	Temperature- controlled	Temperature- controlled	Temperature-controlled	Identical
Electrode Cooling System	Cooling system included and available during RF ablation	Cooling system included and available during RF ablation	Cooling system included and available during RF ablation	Identical

510k Summary

Spinery™ RF Ablation System
by
Axon Spine Medical Systems

	SUBJECT DEVICE	PRIMARY PREDICATE	SECONDARY PREDICATE	Identical/ Substantially Equivalent (SE)
	Spinery™ RF Ablation System	**OsteoCool™ RF Ablation System (K182497)**	**OptaBlate™ RF Ablation System (K221074)**	
Infusion System	Manual Infusion System Included	No Infusion System	Manual Infusion System Included	Identical to Secondary Predicate
System Components	Thermocouple monitor and introducer, peristaltic pump and tube kit, connector hub, footswitch, bone access kit	Thermocouple monitor and introducer, peristaltic pump and tube kit, connector hub, footswitch, bone access kit	Introducer, Ablation Probes, tube kit, connector cable, 11G drill, Temperature Sensor	Identical

Non-Clinical Testing Summary

Performance testing has been completed to demonstrate substantial equivalence of the subject Spinery™ RF Ablation System to the predicate devices, as well as demonstrates the safety of the subject device and that it complies with the recognized standards as specified. The system components were subject to the following verification and validation tests, as applicable:

- **Mechanical**: Mechanical testing was completed on the Spinery™ RF Ablation System after sterilization and shelf life testing including both 1 and 5 year accelerated aging verifying functional integrity of the system. These test included both the Bone Access Kit and the Spinery™ RF Needles.

- **Electrical**: Electrical verification testing was conducted for the subject Spinery™ RF Ablation System to ensure compliance with mechanical requirements of IEC 60601-1: 2014, IEC 60601-2-2: 2018.

- **Electromagnetic Compatibility**: Electromagnetic compatibility (EMC) testing was completed for the applicable components of the subject Spinery™ RF Ablation System. The results demonstrated compliance of the subject system to current IEC 60601-1-2 standard requirements.

- **Sterilization and Shelf Life**: Sterilization validation and shelf life verification testing were conducted for the applicable components of subject Spinery™ RF Ablation System to ensure the components and packaging meet an SAL of 10^{-6} and meet the sterile barrier requirements at the proposed 5 year shelf life per ISO 11607-1 and ASTM F1980 and Ethylene Oxide sterilization requirements per ISO 11135:2020.

- **Biocompatibility**: Biocompatibility verification was performed for patient-contacting components of the Spinery™ RF Ablation System in accordance with current ISO 10993-1 requirements per GLP.

- **Pyrogen**: The Spinery™ RF Ablation Kit and Spinery Thermocouple Monitor Kit are supplied non-pyrogenic. LAL testing using the Kinetic Chromogenic method will be conducted on every lot to verify that devices are non-pyrogenic. The devices meet current FDA and USP pyrogen limit specifications. All test requirements were met as specified by applicable standards and the test protocols.

- **Thermocouple temperature accuracy and Impedance**: Verification testing demonstrated that the relevant components of the subject Spinery™ RF Ablation system achieves accurate temperature measurements, expected impedance measurements and intended area and volume of ablation as per specified test requirements.

- **Usability**: Testing was performed to verify and validate the usability requirements of the subject Spinery™ RF Ablation System.

- **Software**: The applicable software verification and validation was completed for the Spinery RF Generator based on a Major Level of Concern classification for the device. FDA's "Guidance for the content of premarket submissions for software contained in Medical Devices" (May-2005) was used to determine the Level of Concern for the devices.

Conclusions

The performance data supports the safety of the device and demonstrates that the subject device complies with the recognized standards as specified. In summary, we believe the Spinery is substantially equivalent to the predicate devices with respect to the general design approach, function, and the intended use. Differences between subject device and predicate do not negatively affect the safety and effectiveness of the subject device and raise no new questions of safety or effectiveness.