September 23, 2022

Alphatec Spine, Inc.
Sandy Gill
Sr. Regulatory Affairs Specialist
1950 Camino Vido Roble
Carlsbad, CA 92008

Re: K221821
Trade/Device Name: ATEC IOM Accessory Instruments
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: PDQ, ETN
Dated: August 29, 2022
Received: August 30, 2022

Dear Sandy Gill:

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,

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K221821

Device Name
ATEC IOM Accessory Instruments

Indications for Use *(Describe)*
The ATEC IOM Accessory Instruments are utilized in spine surgical procedures to assist in location of the nerves during or after preparation and placement of implants (intervertebral fusion cages and pedicle screw fixation devices) in open and percutaneous minimally invasive approaches.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER:

Alphatec Spine, Inc.
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Phone: (760) 431-9286
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Contact Person: Sandy Gill
Sr. Regulatory Affairs Specialist

Date Summary Prepared: August 29, 2022

II. DEVICE

Trade or Proprietary Name:	ATEC IOM Accessory Instruments
Common Name:	Surgical nerve stimulator/locator
Classification Name:	Neurosurgical Nerve Locator
Regulation Number:	21 CFR 874.1820
Classification:	Class II
Product Code:	PDQ, ETN

III. LEGALLY MARKETED PREDICATE DEVICES

Primary Predicate Device:

510(k)	Product Name	Clearance Date
K191723	ATEC IOM Accessory Instruments	October 18, 2019

Additional Predicate Devices:

510(k)	Product Name	Clearance Date
K171807	ES2 Neuromonitoring Accessory Instruments	July 18, 2017
K110989	Neurovision Ink Printed Endotracheal Tube Electrode	November 03, 2011
K212166	ISIS Headbox 5042XX and ISIS Neurostimulator	January 07, 2022

IV. DEVICE DESCRIPTION

The *ATEC IOM Accessory Instruments* are surgical instruments that provide electrical stimulation to the body to locate and identify nerves in either open, minimally invasive, or percutaneous procedures. These surgical instruments are compatible with common FDA cleared neuromonitoring platforms as they are connected via a compatible clip or probe depending on the system. The neuromonitoring capability provides the surgeon with spinal nerve location, proximity, and integrity information. This information assists the surgeon during targeting, bone preparation, and placement of orthopedic implants such as intervertebral fusion devices (e.g., interbodies) and bone screws (e.g., pedicle screws). All sterile instruments are single use only and all reusable instruments are offered non-sterile to be steam sterilized by the end user.

The purpose of this submission is to gain clearance for new dilators made of conductive sliver ink, aluminum alloy, and dielectric coating.

V. INDICATIONS FOR USE

The *ATEC IOM Accessory Instruments* are utilized in spine surgical procedures to assist in location of the nerves during or after preparation and placement of implants (intervertebral fusion cages and pedicle screw fixation devices) in open and percutaneous minimally invasive approaches.

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The technological design features of the subject implants were compared to the predicates in intended use, indications for use, design, function and technology and it was demonstrated that they are substantially equivalent. See **Table 1** below.

Table 1: Summary of Technological Comparison to Predicates

Attribute	Primary Predicate K191723	Additional Predicate K171807	Additional Predicate K110989	Additional Predicate K212166	Subject Device
	ATEC IOM Instruments	Stryker ES2 Neuromonitoring Accessory Instruments	Neurovision Ink Printed Endotracheal Tube Electrode	ISIS Headbox 5042XX and ISIS Neurostimulator	ATEC IOM Instruments
Indications for Use	The ATEC IOM Accessory Instruments are utilized in spine surgical procedures to assist in location of the nerves during or after preparation and placement of implants (intervertebral fusion cages and pedicle screw fixation devices) in open and percutaneous minimally invasive approaches.	The ES2 Neuromonitoring instruments (Awls, Taps, Screwdriver and LITe Y-NEEDLE 200, 300 and 400) can be used by the surgeon to assist in location of the spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws in open and percutaneous minimally invasive posterior surgical approaches of the non-cervical spine.	The Neurovision Ink Printed Endotracheal Tube Electrode is intended for use during surgery and parasurgical care only, with any compatible monitoring system, for continuous EMG monitoring and status assessment of the nerves supplying the laryngeal musculature as well as providing an open airway for patient ventilation.	ISIS Headbox 5042xx products: The products are intended for intraoperative neuromonitoring; for recording of electrophysiological signals and stimulating of nerve and muscle tissues. The products are intended for use in the operating room to measure and display the electrical signals generated by muscle, peripheral nerves and the central nervous system. The products support the clinical application of Electroencephalography(EEG), Electromyography (EMG), Somatosensory Evoked Potentials (SEP), Motor Evoked Potentials (MEP), and Auditory Evoked Potentials (AEP).The products are not intended for monitoring life-sustaining functions. ISIS Neurostimulator 504180: The ISIS Neurostimulator is intended for provision of neurophysiological stimulation when used in surgical procedures and for diagnostics. It is suitable for continuous operation and can be used in	The ATEC IOM Accessory Instruments are utilized in spine surgical procedures to assist in location of the nerves during or after preparation and placement of implants (intervertebral fusion cages and pedicle screw fixation devices) in open and percutaneous minimally invasive approaches.

Attribute	Primary Predicate K191723	Additional Predicate K171807	Additional Predicate K110989	Additional Predicate K212166	Subject Device
	ATEC IOM Instruments	Stryker ES2 Neuromonitoring Accessory Instruments	Neurovision Ink Printed Endotracheal Tube Electrode	ISIS Headbox 5042XX and ISIS Neurostimulator	ATEC IOM Instruments
				the following fields:– Transcranial electrical stimulation (TES)– Direct cortical stimulation (DCS)– Direct nerve stimulation (DNS) – Transcutaneous electrical nerve stimulation (TNS) – Direct muscle stimulation (DMS)	
Regulation Number, Product Code, & Classification	21 CFR 874.1820 PDQ, ETN Class II	21 CFR 874.1820 PDQ Class II	21 CFR 874.1820 ETN, BTR, GWF Class II	21 CFR 882.1870 GWF, ETN, GWE, GWJ, GWQ, IKN	21 CFR 874.1820 PDQ, ETN Class II
IEC 60601 Compliant	Yes Protected Pin Design via compatible clip/probe Clause 56.3(c)	Yes Protected Pin Design via compatible clip/probe Clause 56.3(c)	Unknown	Yes	Yes Protected Pin Design via compatible clip/probe Clause 56.3(c)
Instrument Type (Description)	Drills/Taps, Awls, Probes, Screwdrivers, Dilators (Sleeves), Guidewires, and Needles	Awls, Taps, Screwdrivers, Guidewires (K-wires), and 200, 300, 400 LITe Y-Needles	ET Tube	ISIS Xpert®Plus, ISIS Xpert®, ISIS Xpress Accessories	Drills/Taps, Awls, Probes, Screwdrivers, Dilators (Sleeves), Guidewires, and Needles
Biocompatibility Patient Contact Duration	Limited patient duration contact (≤ 24 hours)	Limited patient duration contact (≤ 24 hours)	Limited patient duration contact (≤ 24 hours)	Unknown	Limited patient duration contact (≤ 24 hours)
Surgical approach	Open or Percutaneous/Minimally Invasive	Open or Percutaneous/ Minimally Invasive	Unknown	Unknown	Open or Percutaneous/Minimally Invasive
Sterility	Sterile via EtO and non-sterile Non-sterile devices are provided with validated steam sterilization	Sterile and Non-sterile Non-sterile devices are provided with validated steam sterilization	Sterile	Unknown	Sterile via EtO and non-sterile Non-sterile devices are provided with validated steam sterilization

Attribute	Primary Predicate K191723	Additional Predicate K171807	Additional Predicate K110989	Additional Predicate K212166	Subject Device
	ATEC IOM Instruments	Stryker ES2 Neuromonitoring Accessory Instruments	Neurovision Ink Printed Endotracheal Tube Electrode	ISIS Headbox 5042XX and ISIS Neurostimulator	ATEC IOM Instruments
	parameters to assure an SAL of 10^{-6}	parameters to assure an SAL of 10^{-6}			parameters to assure an SAL of 10^{-6}
Reusable/Single Use	Guidewires, Targeting Needles and Dilators – Single Use SafeOp Ball Tip Probe – Single Use Awls, Drills/Taps, Probes, Dilators (Sleeves), and Screwdrivers – Reusable	200, 300, and 400 LITe Y Needles – Single Use Awls, Taps, and Screwdrivers - Reusable	Single Use	Unknown	Guidewires, Targeting Needles and Dilators – Single Use SafeOp Ball Tip Probe – Single Use Awls, Drills/Taps, Probes, Dilators (Sleeves), and Screwdrivers – Reusable
Compatible with Common Neuromonitoring Consoles & Software	Yes	Yes	Yes	N/A includes Neuromonitoring Console and Software	Yes
Minimum exposed surface area	8.6 mm^2	0.53 mm^2	Unknown	2.0 mm^2	5.94mm^2

VII. PERFORMANCE DATA

Performance testing includes IEC 60601-1 testing, and functional testing on insulation effectiveness and electrical resistance. ***Table 2*** summarizes testing that was performed on the subject device to show substantial equivalence to the predicate devices. Testing results demonstrated the subject *ATEC IOM Accessory Instruments* are appropriate for neuromonitoring applications and are substantially equivalent when compared to other legally marketed devices cleared by FDA.

Table 2: Summary of Performance Testing

Test	Test Method Summary	Results
Electrical Safety Testing and/or Evaluation	Evaluation and testing was performed on the subject devices in accordance with IEC 60601-1: 2005(R)2012.	All samples passed acceptance criteria
Functional Performance Testing and Verification Analysis	• Insulation Effectiveness • Electrical Resistance	All samples passed acceptance criteria
Reprocessing	• Cleaning validation or adoption study based on acceptance criteria from AAMI TIR30:2011 • Steam sterilization validation or adoption performed per ANSI/AAMI/ISO 17665-1:2006/(R)2013.	All samples passed acceptance criteria

Clinical Information
Not applicable; determination of substantial equivalence is not based on an assessment of clinical performance data.

VIII. BIOCOMPATIBILITY DATA

A risk analysis was performed taking into account nature of body contact and duration to categorization the use of existing data, end-specific testing, and endpoint assessment to cover the identified test methods. Additionally, data was leveraged by other means (e.g., authorized use of Master File, predicate and reference devices, well known and characterized materials) to support the biocompatibility of the subject devices.

Biocompatibility testing evaluated per ISO 10993-1.

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous
- Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity

In conclusion, the *ATEC IOM Accessory Instruments* are manufactured from the same materials as other legally US-marketed devices.

IX. CONCLUSION

Based upon the information provided in this 510(k) submission, it has been determined that the subject devices are substantially equivalent to legally marketed devices in regards to indications for use, intended use, design, technology, and performance.