Alphatec Spine, Inc
Jeremy Markovich
Senior Manager, Regulatory and Clinical Affairs
5818 El Camino Real
Carlsbad, California 92008

May 9, 2019

Re: K182617
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: April 5, 2019
Received: April 8, 2019

Dear Jeremy Markovich:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

for
Carlos L. Peña, PhD, MS
Director
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K182617

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

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

## I. SUBMITTER:

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5818 El Camino Real
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Phone: (760) 431-9286
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Contact Person: Jeremy Markovich
Senior Manager, Regulatory and Clinical Affairs
Contact Phone: (760) 431-9286

Date Summary Prepared: May 8, 2019

## 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

Predicate Device(s):

| 510(k) | Product Name | Clearance Date |
|---|---|---|
| K171807 | Stryker ES2 Neuromonitoring Accessory Instruments | July 18, 2017 |
| K142438 | Pioneer Surgical Nerve Monitoring Cable System | March 5, 2015 |
| K182542 | The EPAD 2 System | February 22, 2019 |

Reference Device(s):

| 510(k) | Product Name | Clearance Date |
|---|---|---|
| K183705 | IdentiTi Porous Ti Interbody System | March 1, 2019 |
| K161363 | Arsenal Posterior Fixation System | June 10, 2016 |
| K133221 | Arsenal Posterior Fixation System | March 13, 2014 |
| K123623 | Illico MIS Posterior Fixation System | February 14, 2013 |
| K110170 | Raptor Facet Fixation System | November 28, 2011 |

## 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).

**Table 1: Comparison for Substantial Equivalence**

| Attribute | Predicate Device K171807<br>Stryker ES2 Neuromonitoring Accessory Instruments | Predicate Device K142438<br>Pioneer Surgical Nerve Monitoring Cable System | Predicate Device K182542<br>The EPAD 2 System | Subject Device<br>ATEC IOM Instruments |
|---|---|---|---|---|
| **Indications for Use** | 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 Nerve Monitoring Cable in conjunction with dilators, pedicle probes, taps, awls or screw drivers, are intended for tissue dilation/dissection and stimulation of peripheral nerves including spinal nerve roots for location and identification during spinal surgery.<br><br>The dilators are also intended for use in surgical procedures to provide surgical access by dilating the soft tissue to the intended surgical site to allow passage of current from a point on the proximal end to an uninsulated portion of the distal tip. The purpose of this is to allow controlled monitoring of neural elements near and around the point of access. The dilators are offered sterile/single use. | The EPAD 2 system is intended for use in monitoring neurological status by recording somatosensory evoked potentials (SSEP), electromyography (EMG), or assessing the neuromuscular junction (NMJ). Neuromonitoring procedures include intracranial, extracranial, intratemporal, extratemporal, neck dissections, upper and lower extremities, spinal degenerative treatments, pedicle screw fixation, intervertebral fusion cages, rhizotomy, orthopedic surgery, open or percutaneous, lumbar, thoracic, and cervical surgical procedures. | 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. |
| **Regulation, Product Code, & Class** | 21 CFR 874.1820<br>PDQ<br>Class II | 21 CFR 874.1820<br>21 CFR 882.1350<br>PDQ, ETN, GXZ<br>Class II | 21 CFR 882.1870<br>21 CFR 874.1820<br>21 CFR 882.1350<br>21 CFR 882.1320<br>GWF, ETN, PDQ, GXY, GXZ<br>Class II | 21 CFR 874.1820<br>PDQ, ETN<br>Class II |
| **IEC 60601 Compliant** | Yes<br>Protected Pin Design via compatible clip/probe<br>Clause 56.3(c) | Yes<br>Protected Pin Design via compatible clip/probe<br>Clause 56.3(c) | Yes<br>Protected Pin Design via compatible clip/probe<br>Clause 56.3(c) | Yes<br>Protected Pin Design via compatible clip/probe<br>Clause 56.3(c) |

| | | | | |
|---|---|---|---|---|
| **Instrument Type (Description)** | Awls, Taps, Screwdrivers, Guidewires (K-wires), and 200, 300, 400 LITe Y-Needles | Dilators, Pedicle Probes, Taps, Awls and Screwdrivers | Probes, Dilators, Electrodes | 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) | Limited patient duration contact (≤ 24 hours) |
| **Biocompatible** | Yes (Characterizatio | Yes | Yes | Yes |
| **Surgical Approach** | Open or Percutaneous/ Minimally Invasive | Open or Percutaneous/ Minimally Invasive | Open or Percutaneous/ Minimally Invasive | Open or Percutaneous/ Minimally Invasive |
| **Sterility** | Sterile and Non-sterile<br><br>Non-sterile devices are provided with validated steam sterilization parameters to assure an SAL of $10^{-6}$ | Sterile and Non-sterile<br><br>Non-sterile devices are provided with validated steam sterilization parameters to assure an SAL of $10^{-6}$ | Sterile and Non-sterile | Non-sterile<br><br>Non-sterile devices are provided with validated steam sterilization parameters to assure an SAL of $10^{-6}$ |
| **Reusable/ Single Use** | 200, 300, and 400 LITe Y Needles – Single Use<br><br>Awls, Taps, and Screwdrivers - Reusable | Dilators – Single Use<br><br>Pedicle probes, taps, awls and screw drivers – Reusable | Single Use | Guidewires, Targeting Needles and Dilators – Single Use<br><br>Awls, Drills/Taps, Probes, Dilators (Sleeves), and Screwdrivers – Reusable |
| **Compatible with Common Neuromonitoring Consoles & Software** | Yes | Yes | Yes | Yes |
| **Connection to Neuromonitoring Unit** | Clip or probe (based on Neuromonitoring system) | Clip or probe (based on Neuromonitoring system) | Clip or probe (based on Neuromonitoring system) | Clip or probe (based on Neuromonitoring system) |
| **Minimum exposed surface area during tissue stimulation** | 0.53 $mm^2$ | 12.9032 $mm^2$ (0.02 $in^2$) | Unknown | 8.6 $mm^2$ |

**Table 2: Comparison for Substantial Equivalence for Reference Device(s)**

| Attribute | Reference Device K183705 | Reference Device K110170 | Reference Device K123623 | Reference Device K133221 K161363 | Subject Device |
|---|---|---|---|---|---|
| | **IdentiTi Porous Ti Interbody System** | **Raptor Facet Fixation System** | **Illico MIS Posterior Fixation System** | **Arsenal Posterior Fixation System** | **ATEC IOM Instruments** |
| **Regulation, Product Code, & Class** | 21 CFR 888.3080<br>MAX<br>Class II | 21 CFR 888.4540<br>LXH<br>Class I | 21 CFR 888.4540<br>LXH<br>Class I | 21 CFR 888.4540<br>LXH<br>Class I | 21 CFR 874.1820<br>PDQ, ETN<br>Class II |
| **Instrument Type (Description)** | Inserter | Screwdrivers, Guidewires | Guidewires, Dilators (Sleeves) | Screwdrivers | Drills, Taps, Awls, Probes, Screwdrivers, Dilators (Sleeves), Guidewires, and Targeting Needles |
| **Biocompatibility Patient Contact Duration** | Limited patient duration contact (≤ 24 hours) | Limited patient duration contact (≤ 24 hours) | Limited patient duration contact (≤ 24 hours) | Limited patient duration contact (≤ 24 hours) | Limited patient duration contact (≤ 24 hours) |
| **Biocompatible** | Yes (Data provided to characterize materials) | Yes (Data provided to characterize materials) | Yes (Data provided to characterize materials) | Yes (Data provided to characterize materials) | Yes |
| **Sterility** | Non-sterile<br><br>Non-sterile devices are provided with validated steam sterilization parameters to assure an SAL of $10^{-6}$ | Non-sterile<br><br>Non-sterile devices are provided with validated steam sterilization parameters to assure an SAL of $10^{-6}$ | Non-sterile<br><br>Non-sterile devices are provided with validated steam sterilization parameters to assure an SAL of $10^{-6}$ | Non-sterile<br><br>Non-sterile devices are provided with validated steam sterilization parameters to assure an SAL of $10^{-6}$ | Non-sterile<br><br>Non-sterile devices are provided with validated steam sterilization parameters to assure an SAL of $10^{-6}$ |
| **Reusable/ Single Use** | Inserter – Reusable | Guidewires - Single Use<br>Screwdrivers – Reusable | Guidewires - Single Use<br>Dilator – Reusable | Screwdrivers – Reusable | Guidewires, Targeting Needles and Dilators – Single Use<br><br>Awls, Drills/Taps, Probes, Dilators (Sleeves), and Screwdrivers – Reusable |
| **Compatible with Common Neuromonitoring Consoles & Software** | No | No | No | No | Yes |

| | | | | | |
|---|---|---|---|---|---|
| **Connection to Neuromonitoring Unit** | Not applicable | Not applicable | Not applicable | Not applicable | Clip or probe (based on Neuromonitoring system) |

## 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.

## VII. PERFORMANCE DATA

Performance testing demonstrates the subject *ATEC IOM Accessory Instruments* are appropriate for neuromonitoring applications and do not introduce a new worst case for minimum exposed surface area during tissue stimulation compared to other legally marketed devices cleared by FDA.

The table below summarizes the testing which was performed on the subject devices to show substantial equivalence to the predicate devices.

| Test | Test Method Summary | Results |
|---|---|---|
| **Functional performance testing and verification analysis** | • Insulation Effectiveness<br>• Electrical Resistance<br>• Current Density | All functional performance testing passed. Substantial equivalence has been shown via analysis and testing. |
| **Electrical safety testing and/or evaluation** | Evaluation and testing was performed on the subject devices in accordance with IEC 60601-1: 2005. | Subject devices passed electrical safety testing and/or evaluation, demonstrating that the devices meet the requirements. |
| **Biocompatibility testing** | Biocompatibility testing conducted per ISO 10993.<br>• Cytotoxicity<br>• Sensitization<br>• Irritation/Intracutaneous Reactivity<br>• Acute Systemic Toxicity<br>• Material Mediated Pyrogenicity<br>• Hemocompatibility | 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. |
| **Reprocessing** | • Cleaning validation study based on acceptance criteria from AAMI TIR30:2011<br>• Steam sterilization validation performed per ANSI/AAMI/ISO 17665-1:2006/(R)2013. | The subject devices can be adequately cleaned and steam sterilized prior to use. |

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

## VIII. 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.