October 1, 2021

IotaMotion, Inc.
℅ Deborah Arthur
Regulatory Consultant to iotaMotion
DArthurConsulting
231 Queens Rd
Charlotte, North Carolina 28204

Re: DEN190055
Trade/Device Name: iotaSOFT Insertion System - Drive Unit, Controller and Accessories
Regulation Number: 21 CFR 874.4450
Regulation Name: Powered insertion system for a cochlear implant electrode array
Regulatory Class: Class II
Product Code: QQH
Dated: December 17, 2019
Received: December 18, 2019

Dear Deborah Arthur:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the iotaSOFT Insertion System - Drive Unit, Controller and Accessories ("iotaSOFT Insertion System"), a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The iotaSOFT™ Insertion System is intended to aid the surgeon in placement of cochlear implant electrode arrays into a radiographically normal cochlea by controlling the speed of implant insertion. The iotaSOFT Insertion System is intended for use in cochlear implant patients ages 12 years and older during cochlear implant procedures using either a round window or cochleostomy approach.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the iotaSOFT Insertion System, and substantially equivalent devices of this generic type, into Class II under the generic name powered insertion system for a cochlear implant electrode array.

FDA identifies this generic type of device as:

> **Powered insertion system for a cochlear implant electrode array**. A powered insertion system for a cochlear implant electrode array is a prescription device used to assist in placing an electrode array into the cochlea.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On December 18, 2019, FDA received your De Novo requesting classification of the iotaSOFT Insertion System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the iotaSOFT Insertion System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the iotaSOFT Insertion System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	**Mitigation Measures**
Risks to health relating to device interface with patient anatomy, including: • Damage to skull tissue • Damage to dura mater • Bone damage • Cerebrospinal fluid leak • Damage to cochlea; hearing loss, tinnitus, vertigo	Clinical performance testing Usability testing Non-clinical performance testing Labeling
Cochlear implant insertion failure leading to: • Trauma to cochlear structures resulting in residual hearing loss or nerve degeneration • Suboptimal array placement (including array rotation) leading to poor hearing performance • Failure to disengage from cochlear implant at end of procedure, leading to manual correction and insertion	Clinical performance testing Non-clinical performance testing Usability testing Cochlear implant compatibility validation Software verification, validation, and hazard analysis Labeling
Damage to cochlear implant during insertion leading to poor cochlear implant performance and/or compromised implant reliability	Non-clinical performance testing Usability testing Cochlear implant compatibility validation

	Shelf life testing Software verification, validation, and hazard analysis Labeling
Adverse tissue reaction, including irritation / inflammation of surgical site	Biocompatibility evaluation
Electromagnetic interference, thermal injury, or electric shock	Electrical safety testing Electromagnetic compatibility (EMC) testing Labeling
Infection	Sterilization validation Shelf life testing Labeling
Excessive operation time leading to increased exposure to anesthesia	Clinical performance testing Usability testing Labeling

In combination with the general controls of the FD&C Act, the powered insertion system for a cochlear implant electrode array is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including evaluation of all adverse events.
(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include:
    (i) Verification of cochlear implant attachment force, release force and insertion speed;
    (ii) Testing to demonstrate the device does not damage or degrade the cochlear implant (including the lead and array portions of the cochlear implant);
    (iii) Comparison testing with manual insertion to evaluate:
        (A) Differences in cochlear implant array insertion force associated with use of the device; and
        (B) Intracochlear placement of the cochlear implant array (intended scala placement and array insertion depth, together with minimal array tip foldover and cochlear scala translocation).
(3) Usability testing in a simulated hospital environment with an anatomically relevant model (e.g., cadaver testing) that evaluates the following:
    (i) Successful use to aid in placement of the electrode array into the cochlea; and
    (ii) Harms caused by use errors observed.
(4) Changes in cochlear implant compatibility are determined to significantly affect the safety or effectiveness of the device and must be validated through performance testing or a rationale for omission of any testing.
(5) The patient-contacting components of the device must be demonstrated to be biocompatible.
(6) Performance testing must demonstrate the electromagnetic compatibility (EMC), electrical safety, and thermal safety of the device.
(7) The patient-contacting components of the device must be demonstrated to be sterile and non-pyrogenic.

(8) Performance testing must support the shelf life of device components provided sterile by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.
(9) Software verification, validation, and hazard analysis must be performed for any software components of the device.
(10) Labeling must include:
  (i) The recommended training for the safe use of the device;
  (ii) Summary of the relevant clinical and non-clinical testing pertinent to use of the device with compatible electrode arrays; and
  (iii) A shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the powered insertion system for a cochlear implant electrode array they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Vasant Dasika, Ph.D. at 301-796-5365.

Sincerely,

Eric A. Mann -S

for Malvina Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health