January 9, 2026

iotaMotion, Inc.
% Deborah Arthur
Regulatory Consultant
DArthur Consulting
5355 Pinehurst Park Dr.
#393
Charlotte, North Carolina 28211

Re: K252339
Trade/Device Name: iotaSOFT® Insertion System
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 12, 2025
Received: December 12, 2025

Dear Deborah Arthur:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joyce C. Lin -S

for 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252339

Please provide the device trade name(s).

iotaSOFT® Insertion System

Please provide your Indications for Use below.

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 array insertion. The iotaSOFT Insertion System is indicated for use in cochlear implant patients ages 4 years and older during cochlear implant procedures using either a round window or cochleostomy approach.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

4205 White Bear Parkway, Suite 600
St. Paul, MN 55110

iotaSOFT® Insertion System Expansion of Indications to include: Ages 4 – 12 years

510(k) Summary

K252339

1. DEVICE [PER 807.92(a)(2)]

Name of Device: iotaSOFT® Insertion System

Classification Name: Powered insertion system for a cochlear implant electrode array

Common Name: iotaSOFT Insertion System

Regulation: 21 CFR §874.4450

Regulatory Class: II

Product Code: QQH

Date Prepared: January 9, 2026

2. PREDICATE DEVICE [PER 807.92(a)(3)]

Predicate Device Name:

iotaSOFT Insertion System – Drive Unit, Controller and Accessories

Manufacturer: iotaMotion, Inc.

Submission Number: DEN190055

This predicate has not been subject to a design-related recall.

The subject device is identical to the predicate in design, materials, software, and intended use, with the only change being an expansion of the indicated patient population to include pediatric patients aged 4 to 12 years.

3. DEVICE DESCRIPTION [PER 807.92(a)(4)]

The iotaSOFT® Insertion System is designed to assist the surgeon during cochlear implantation by controlling the speed of electrode array insertion. The iotaSOFT Insertion System is designed to reduce electrode array insertion variability and forces. The system includes:

- Sterile single-use Drive Unit (IM-00 or IM-05)
- Reusable, nonsterile touch screen console and footpedal interface

The Drive Unit is mounted on a standard surgical equipment Rolling Stand and is compatible with commercially available cochlear implant arrays from each of the 3 CI manufacturers distributing product in the U.S.

4. Intended 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.

5. Indications for Use

Indications for Use (Expanded)

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 array insertion. The iotaSOFT Insertion System is indicated for use in cochlear implant patients aged 4 years and older during cochlear implant procedures using either a round window or cochleostomy approach.

6. Comparison of Technological Characteristics with the Predicate

There are no changes to the technological characteristics of the iotaSOFT Insertion System compared to the predicate device. The technological characteristics, e.g., features, parameter settings etc. are the same as the predicate and thus substantially equivalent. **Table 1** summarizes the characteristics of the iotaSOFT Insertion System (subject device) in comparison to that of the predicate.

Table 1 Summary of Substantial Equivalence

	Subject Device	Predicate	Discussion
Device Trade Name	**iotaSOFT Insertion System**	**iotaSOFT Insertion System**	
510k Number	K252339	DEN190055	
Product code	QQH	QQH	Same as predicate
Regulation number	21 CFR 874.4450	21 CFR 874.4450	Same as predicate
Regulation name	Powered insertion system for a cochlear implant electrode array	Powered insertion system for a cochlear implant electrode array	Same as predicate
Intended 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 to aid the surgeon in placement of cochlear implant electrode arrays into a radiographically normal cochlea by controlling the speed of implant insertion.	Same as predicate

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	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 array insertion. The iotaSOFT Insertion System is indicated for use in cochlear implant patients aged 4 years and older during cochlear implant procedures using either a round window or cochleostomy approach	Same as predicate with the only change is the expansion of the minimum age for indication from '*12 years and older*' down to '*4 years and older*'. A clinical study for safety and effective use of iotaSOFT and a usability justification conducted on the predicate population was documented for the expansion, pediatric population. Use of the device with the younger CI candidates did not raise different questions of safety or effective use with iotaSOFT.

7. Non-Clinical Performance Data

As the scope of this premarket notification is to expand the age of inclusion within the iotaSOFT indications (12 years down to 4 years of age), the non-clinical performance 'new' testing was minimal as there was no difference in the Special Control requirements and risk mitigations between the two age groups as the same device systems would be available for all eligible CI candidates and both device Drive Units had completed required standards based testing prior to their market introduction.

The following testing has been performed in accordance with applicable standard/guidance for Drive Unit (IM-05) to support manufacturing process changes:

Test	Summary	Conclusion
Biocompatibility ISO 10993-1	Device Classification: External communicating device, tissue/bone/dentin, ≤24 hr (limited) Endpoints: Cytotoxicity – ISO 10993-5 Sensitization – ISO 10993-10 Irritation – ISO 10993-23 Acute Systemic Toxicity – ISO 10993-11 Materials Mediated Pyrogenicity – ISO 10993-11	Pass – All evaluation criteria were met.
Sterilization ISO 11135	The sterilization process was validated to demonstrate a minimum SAL of 10^{-6} for the product using Ethylene Oxide (EO). EO Residuals testing was completed per ISO 10993-7.	Pass – All criteria passed and the sterilization cycle was validated.

Usability IEC 62366-1	This testing was performed in accordance with FDA guidance, "Applying Human Factors and Usability Engineering to Medical Devices", February 3, 2016. Usability evaluation was completed in a simulated use environment in PHACON model representative of patients in the intended age range. Number of participants: 12 Model: Temporal bone bench model representative of both right and left sided anatomy of 4yr old. Surgical procedure performed: Fixation of the iotaSOFT Drive Unit and cochlear implant insertion. Result/conclusion: 9 of 10 essential tasks were completed by all 12 users.	Pass – The iotaSOFT® Insertion System with IM-05 has been found to be safe and effective for the intended users, uses, and use environments.

8. Clinical Performance Data-Pediatric subjects ages 4 -12 years

The clinical performance data gathered from these children ages 4 to 12 years is supporting evidence of the safety and effective use of the iotaSOFT Insertion System in aiding surgeons with insertion of compatible cochlear implant electrode arrays in the target pediatric population. The study population included 14 children within the target age range who were cochlear implant candidates for one of the multiple iotaSOFT compatible cochlear implants from each of the three major implant manufacturers with FDA approved product and indications for use meeting the same requirements (primarily age) as iotaSOFT. These children were seen across three (3) sites that included eight (8) investigators within a study duration approximately 14 months long and follow-up at postop device activation and then 1-month post-activation. The primary study endpoint was for safety through the 1-month post-activation interval and with secondary and additional analyses incorporating surgeon effective use with iotaSOFT during the CI procedure.

Across the fourteen (14) study subjects, there were four (4) adverse events. None of the adverse events were related to the investigational device or procedure.

- No serious device-related adverse events occurred therefore meeting the primary endpoint.
- One (1) serious adverse event (SAE - not investigative device-related), and
- Three (3) additional non-serious and unrelated to the device or iotaSOFT insertion procedure, adverse events were reported. Two of the three AEs were well documented as 'risks associated with cochlear implant surgery' while the third was an unrelated illness.

All events resolved and did not interfere with the activation and follow-up with the cochlear implant at one-month post-activation.

Additional data analyses obtained via a surgeon self-reporting post-procedure questionnaire affirmed that all the surgeons were able to successfully 'load' the electrode into iotaSOFT with ~93% reporting maintaining visibility of the cochlea while iotaSOFT was in use; no identified tip foldovers or electrode transposition occurred and all electrode arrays achieved the surgeon desired depth of insertion – over 70% with iotaSOFT alone with the remaining reporting full insertion when also incorporating manual insertion into the procedure. While use of postoperative imaging was optional so visualization of electrode array positioning was not always possible, it should be noted that ESRT and impedance measurements were obtained for all subjects at both post-operative intervals.

The data supporting the safety of the iotaSOFT Insertion System when used as intended by the cochlear implanting surgeon in children 4 – 12 years of age is consistent with that seen in the earlier study with CI eligible subjects ages 12 years and older. The absence of device/procedure complications that could affect safety when using iotaSOFT both with the surgeon and the patient in addition to the evidence of the effective use of the device during cochlear implantation is consistent with the benefit-to-risk outcomes as seen with the adult patients.

9. Statement of Substantial Equivalence

The iotaSOFT Insertion System is substantially equivalent to the predicate device with respect to intended use, design, and performance. The expanded pediatric indication is supported by preclinical and clinical evidence. No new questions of safety or effectiveness are raised.

10. Conclusion

The iotaSOFT Insertion System, as modified to include patients aged 4 years and older, is substantially equivalent to the previously cleared predicate (DEN190055). The expanded indication is supported by preclinical and clinical data and does not alter the device's safety or effectiveness.