

**DE NOVO CLASSIFICATION REQUEST FOR
IOTASOFT™ INSERTION SYSTEM - DRIVE UNIT, CONTROLLER AND ACCESSORIES**

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 874.4450

CLASSIFICATION: Class II

PRODUCT CODE: QQH

BACKGROUND

DEVICE NAME: iotaSOFT Insertion System - Drive Unit, Controller and Accessories

SUBMISSION NUMBER: DEN190055

DATE DE NOVO RECEIVED: December 18, 2019

SPONSOR INFORMATION: IotaMotion, Inc.
14 ½ S. Clinton St.
Iowa City, Iowa 52240

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.

LIMITATIONS

The iotaSOFT™ Insertion System is not indicated for use in patients with craniofacial abnormalities, temporal squamosal skull thickness less than 3mm, major cochlear lesions (e.g. fibrosis, fracture, or ossification), or cochlear malformations.

The iotaSOFT™ Insertion System is only intended for use on individuals 12 years of age or older.

The iotaSOFT™ Insertion System is indicated for use only (a) with the Advanced Bionics HiFocus SlimJ, Cochlear Slim Straight, and MED-EL Flex 24 & 28 cochlear implant electrode arrays; and (b) after giving due consideration to all relevant facts and circumstances, including the surgeon’s clinical judgment and the array’s instructions for use, contraindications, limitations for use, and any accompanying surgical guides.

The sale, distribution, and use of the iotaSOFT Insertion System are restricted to prescription use in accordance with 21 CFR 801.109.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The iotaSOFT™ Insertion System is designed to assist the surgeon during cochlear implantation by controlling electrode array insertion speed. The system consists of a single-use, sterile drive unit (*iotaSOFT™ DRIVE Unit*) connected to a reusable, non-sterile touch screen control console and footpedal (*iotaSOFT Controller and Accessories*) (**Figure 1**).

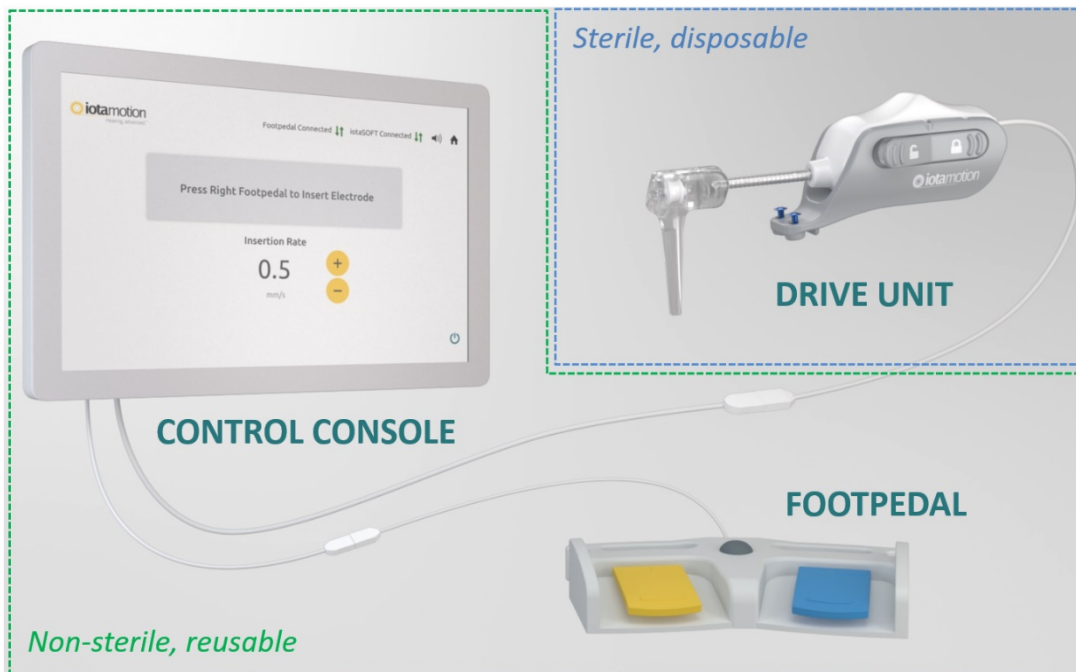


Figure 1: iotaSOFT™ Insertion System Overview: The iotaSOFT™ Insertion System is made up of the three main components shown: User Control Console, Drive Unit (screwdriver not shown), and surgeon footpedal controller. Components within **Blue** dashed region represent components used within the sterile surgical field. **Green** dash region represents components used outside the sterile surgical field.

System Components

iotaSOFT Drive Unit (sterile, disposable)	Drive (Motor) Unit
	Drive Head
	Unit Base
	Self-Drilling Screws x2
	Screw Driver
iotaSOFT Controller and Accessories (non-sterile, reusable)	Touch Screen
	Graphical User Interface
	Rolling Stand Assembly
	Foot pedal
	Accessory Control Console Power Supply
	Accessory USB extender cables x2

SYSTEM COMPONENT DESCRIPTION: iotaSOFT™ DRIVE Unit

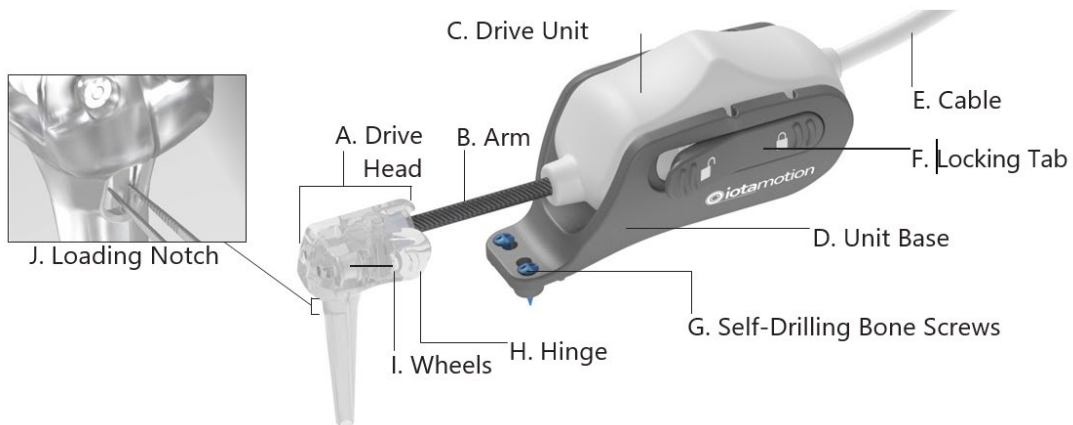


Figure 2: iotaSOFT™ | DRIVE Unit Sub-Components

Drive (Motor) Unit: The Drive Unit is supplied sterile in a tray with Tyvek lid with the screwdriver packaged within. The Drive unit (Figure 2) couples to the electrode lead via the drive head (A) which is linked to a drive cable housed within the semi-rigid, “stay-put” gooseneck arm (B) of the main drive unit (C). The drive unit is held within the unit base (D) that is secured to the patient via self-drilling bone screws (G). The power/ communications cable (E) is passed off the sterile field and connected to the main control console. The drive unit is designed to be adjustable by sliding forward or backwards within the base or removable for electrode loading then replacing and securing into the base with the side locking tabs (F). Based on patient anatomy, the drive head trajectory and angle may also be adjusted by bending the flexible, semi-rigid arm and/or rotating drive head (Figure 3).



Figure 3: iotaSOFT™ | DRIVE Unit adjustability features to manually manipulate drive head position and electrode array insertion trajectory.

Drive Head: The drive head consists of two halves which clamp to the CI electrode lead via spring loaded hinge. The drive wheels are houses within the drive head with the wheel geometries designed to cup around the electrode lead and facilitate loading. The electrode engagement mechanism is compatible with the electrode arrays listed above having multiple and varying lead nominal diameters ranging 0.8 to 1.2mm. The drive head tips are additionally designed with grooved, keyhole inner geometry or track to accommodate for “winged” electrodes to maintain the proper electrode array contact orientation toward the modiolus during insertion (**Figure 4**) The drive head is design with a spring clamp and engagement gap, (~0.38 mm) to prevent over-compressing the electrode lead. A forceps loading notch is incorporated which increases ease of electrode coupling to the drive head. The loading notch allows both closure of the drive head halves around the electrode while being held with forceps and enables subsequent release of the forceps without re-opening the drive head. The drive head tip is tapered for improved operative views and made of a semi-transparent polycarbonate plastic which allows visualization of the electrode within the drive tips and operative light transmission.



Figure 4: iotaSOFT | Drive Head representation of drive wheels (right) and clasping hinge coupling mechanism to electrode lead (left).

Unit Base: The unit base provides an adjustable yet stable and secure platform for the drive unit to sit within. The base holds the main drive unit and enables smooth, sliding adjustments with dual locking side toggle tabs. The base inner well “cupped” design allows the drive unit to securely slide within the base yet enables one-handed installation or removal of the unit. Similarly, the dual locking side tabs add additional stabilization once the desired unit positioning has been achieved. Additionally, the base “foot” region holds the pre-loaded, semi-captive screws. The geometry of the base and contact angle of the “foot region” is designed to match curvature of the skull and sit over skin flap between base and skull bone (**Figure 5**).

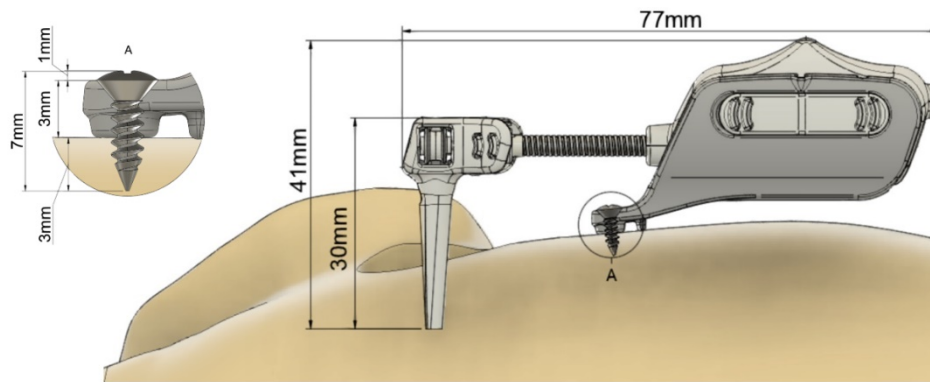


Figure 5: iotaSOFT™ | DRIVE Unit Dimensions: Approximate dimensions in mm.

Screwdriver & Self-Drilling Screws: Screwdriver is provided sterile to screw the self-drilling screws x2 into the skull to secure and stabilize the unit base. The bone screws are self-drilling titanium bone screws with nominal outer diameter of 1.5mm and nominal length of 7mm (**Figure 5**). The bone screws are preloaded and semi-captive in unit base by a retaining silicone plug. When used as intended in combination within the unit base the screw functional length into skull is limited to maximum depth of 3mm.

SYSTEM COMPONENT DESCRIPTION: iotaSOFT™ Controller & Accessories

Touch screen control console with Graphical User Interface (GUI): The Control console (**Figure 6**) provides power and communication across iotaSOFT™ system components including the Drive unit and surgeon foot pedal. The console consists of an all-in-one computer with high definition Projected Capacitive (PCAP) touchscreen screen and USB connections for the foot pedal and drive unit cables. The iotaSOFT™ software is directly loaded at startup to operate the DRIVE Unit.

Control Footpedal: The surgeon has handsfree control of the Drive unit and insertion rate setting (0.1mm/sec to 1.0mm/sec) via the non-sterile foot pedal (**Figure 6**). The surgeon controls the CI advancement and retraction using the foot pedal. With left, yellow pedal reversing electrode and right, blue pedal advancing per standard convention. The center, black button can be pressed to access insertion rate control menu and/or select to confirm and close menus.

Accessories: Control console power supply and 2 USB extender cables: The Control Console power supply plugs into the mains power outlet. Two USB 10ft extension cables are secured and connected to the console with excess length coiled on the rolling stand basket (**Figure 6**). The system is designed such that the foot pedal and drive unit cable ends can be connected to either console USB cable pigtails for normal operation.

Rolling Stand Assembly – The rolling stand (**Figure 6**) allows the surgeons to position the Control Console at a convenient location within 3 feet of surgical table for visibility and accessibility during the procedure. The rolling stand assembly includes a basket and a separate control console power supply mounting bracket. (NOTE: console, rolling stand, cable connections, and foot pedal are intended for operation outside of the sterile field).

SUMMARY OF NONCLINICAL/BENCH STUDIES

The non-clinical/bench studies conducted on the iotaSOFT System to demonstrate a reasonable assurance of safety and effectiveness of the device are summarized in the sections below.

BIOCOMPATIBILITY

The iotaSOFT™ Drive Unit components and type of contact are described below. The patient-contacting components of the iotaSOFT™ Drive Unit passed all biocompatibility requirements for an external communicating device in limited contact with tissue/bone/dentin with an exposure duration of limited (<24hr). The following



Figure 6: iotaSOFT | Control console, footpedal, rolling stand assembly with power supply and USB cable extenders.

biocompatibility testing was performed to ensure the safety of the iotaSOFT Insertion System:

- Cytotoxicity
- Irritation
- Sensitization
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Bacterial Endotoxin
- Ethylene Oxide Residuals

The components that come into direct body contact with the patient are the right and left drive housings (in contact with tissue/bone/CSF), the stage base, arm (gooseneck) heat shrink, bone screws, and silicone in contact with tissue/bone. The rest of the disposable device and the reusable components (Control Console and Footpedal) do not come into any direct contact with the patient.

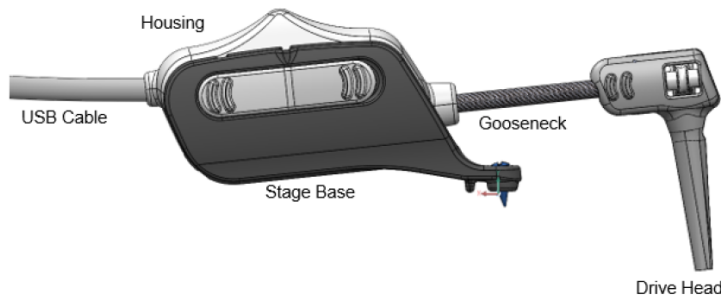


Figure 1. iotaSOFT Drive System Assembled

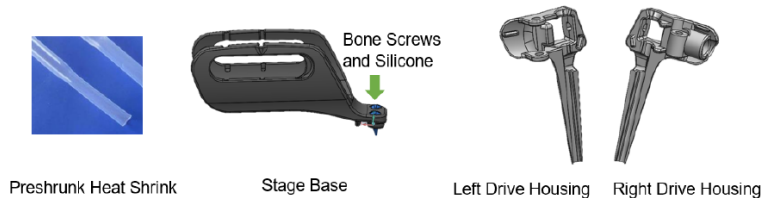


Figure 2. iotaSOFT DRIVE Biocompatible Components

The biocompatibility testing is performed according to the *ISO 10993-1:2009 Biological evaluation of medical devices* and the FDA Guidance Document on *Use of International Standard ISO 10993-1*. FDA guidance includes a modified table from ISO 10993-1 with additional recommended tests.

SHELF LIFE/STERILITY

Sterilization

The reusable components (control console, power supply, footpedal, extension cable and rolling stand) do not contact the patient tissue and thus do not need to be sterilized.

These reusable components are provided non-sterile to the user. Cleaning/disinfection instructions were provided in the Instructions for Use.

The single use components (including the iotaSOFT Drive Unit) are provided sterile to the user. The sterilization method is ethylene oxide (EO). The sterilization validation of the iotaSOFT Drive Unit was performed via adoption per AAMI TIR28. It was demonstrated that the iotaSOFT Drive Unit can be sterilized effectively to a minimum sterilization assurance level (SAL) of 10^{-6} .

The EO and ECH residuals were measured using the iotaSOFT Drive Unit demonstrating that the residual levels comply to the limits specified in ISO 10993-7.

Packaging and Shelf Life

Packaging validation

A representative number of product samples (95% confidence/90% reliability) were subjected to two full cycles of EO, environmental conditioning (per ASTM D4332) and transportation simulation (per ASTM D4169, DC13, AL1). For the package integrity, seal strength (per ASTM F88) and gross leak (per ASTM F2096) testing were performed. All samples met the acceptance criteria (≥ 1 lb/in and no bubble leak).

Shelf life validation

The iotaSOFT Insertion System is labeled with a 6-month shelf life. Product samples (95% confidence/90% reliability) were subjected to two full cycles of EO, environmental conditioning (per ASTM D4332) and accelerated aging (per ASTM F1980, $55^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 19 days). For the package integrity, seal strength (per ASTM F88) and gross leak (per ASTM F2096) testing were performed. All samples met the acceptance criteria (≥ 1 lb/in and no bubble leak).

Non-Pyrogenicity

Endotoxin testing was performed using the LAL kinetic turbidimetric method (AAMI ST72, USP <85> and USP <161>) with the sterilized iotaSOFT Drive Unit. All samples met the acceptance criteria (≤ 2.15 EU/device).

ELECTROMAGNETIC CAPABILITY & ELECTROMAGNETIC SAFETY

The iotaSOFT Insertion System was tested for Electrical Safety and Electromagnetic Compatibility using final production units and the following software and firmware versions: Control Console Software: v1.0.3, PCB Firmware: v0.1.1.

The iotaSOFT Insertion System passed all tests for Electrical Safety and was found compliant with AAMI ES60601-1:2005/(R)2012+A1:2012. All tests and compliance investigations were completed with no alternative risk control measures or test methods employed.

The iotaSOFT Insertion System passed all tests for EMC and was found compliant with IEC 60601-1-2:2014. All tests and compliance investigations were completed with no alternative risk control measures or test methods employed. The table below provides a summary of the tests completed.

Specification	Test Description	Compliance
CISPR 11: 2009 + A1: 2010	Conducted Emissions-Voltage-Class A, Group 1	Compliant
CISPR 11: 2009 + A1: 2010	Radiated Emissions - Class A, Group 1	Compliant
IEC 61000-4-2: 2008	Electrostatic Discharge Immunity	Compliant
IEC 61000-4-3:2006 + A1:2007 + A2:2010	Radiated Electromagnetic Field Immunity	Compliant
	Immunity to proximity fields from RF wireless communications equipment	Compliant
IEC 61000-4-4: 2012	Electrical Fast Transient/Burst Immunity	Compliant
IEC 61000-4-5: 2005	Surge Immunity	Compliant
IEC 61000-4-6: 2013	Conducted Radio-Frequency Immunity	Compliant
IEC 61000-4-11: 2004	Voltage Dips, Interruptions and Variations	Compliant

SOFTWARE

Software/Firmware

Device software and firmware was described, verified and validated. Considerations were taken based on the FDA Guidance Document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”. The iotaSOFT™ Insertion System contains two components housing software, the control console (software) and the Drive Unit (firmware). Device communication (1-way) between the control console and the Foot Pedal is via a wired connection. The control console also conducts (2-way) communication with the Drive unit via a wired connection. The device is in no way connected to the internet or IT Network. No patient data or other sensitive information is held or communicated by the device.

The following software and firmware versions were used for software verification:

- Control Console Software: v1.0.3
- Drive Unit PCB Firmware: v0.1.1

Software documentation, including the following, was provided:

- Software Description/Summary of Functional Requirements from SRS
- Device Hazard Analysis
- Traceability Analysis
- Verification and Validation Documentation
- Revision Level History

Cybersecurity

Cybersecurity was addressed during the design and development of the iotaSOFT Insertion System. Cybersecurity considerations were taken based on the FDA Guidance Documents “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”, and “Postmarket Management of Cybersecurity in Medical Devices.”

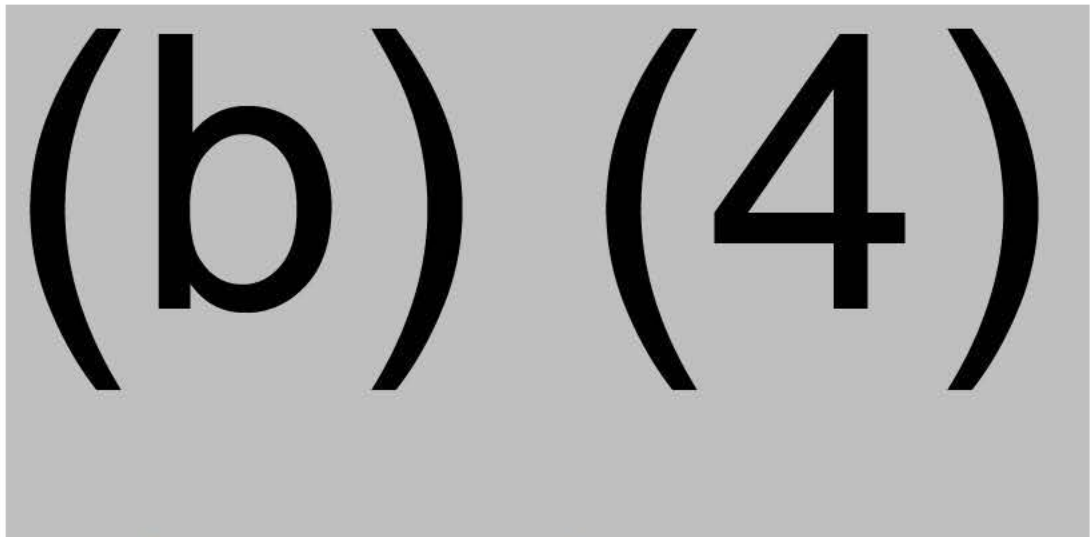


Figure 1: *iotaSOFT System Diagram for Threat Model Analysis*

A cybersecurity threat model analysis was performed for the iotaSOFT Insertion System using the STRIDE method. As a result of the threat analysis, the iotaSOFT Insertion System Hazard Analyses identify the hazards, mitigations, and design considerations pertaining to intentional or unintentional cybersecurity risks associated with the device.

Mechanical testing – unit base attachment screws

Bone screw and screwdriver testing (bench testing): The bone screws used in the iotaSOFT Insertion System to secure the unit base to the skull were characterized per ASTM F543-17 Annex A1 for maximum torque. Bone screws were tested to withstand a maximum torque $\geq 0.2\text{Nm}$ without stalling, stripping, or breaking. The rotational breaking angle, yield torque, yield strength and fracture location were also evaluated at failure, and these parameters exceeded the acceptance criteria with respect to the intended use.

Summary of iotaSOFT performance data (non-clinical and clinical) supporting compatibility with labeled cochlear implants

Four sets of non-clinical performance testing (comprising bench performance, synthetic cochlea insertion force comparison (bench testing), cadaveric comparison, usability/human factors) and one set of clinical performance testing are summarized below. As discussed below, cochlear implant (electrode array) models tested include the following straight arrays:

- MED-EL Flex 24
- MED-EL Flex 28
- Cochlear Slim Straight
- Advanced Bionics (AB) HiFocus SlimJ

Data was provided to support the safe and effective use of iotaSOFT to assist in the insertion of the above cochlear implant electrode arrays (i.e., cochlear implant compatibility validation).

As listed below, iotaMotion conducted four nonclinical validation tests using the MED-EL Flex 24; iotaMotion provided rationale to leverage this testing to support iotaSOFT use with the MED-EL Flex 28 array. iotaMotion asserts the primary difference between the electrode arrays is the additional length of the array portion (4 mm) between the MED-EL Flex 24 and Flex 28, which does not affect compatibility or use with the iotaSOFT. All other dimensions and materials between the MED-EL Flex 24 and Flex 28 arrays/leads are reported by iotaMotion to be identical.

PERFORMANCE TESTING - BENCH

Bench performance testing (verification of device characteristics). Devices having undergone sterilization, accelerated aging and simulated transportation/distribution were tested with the following arrays: Advanced Bionics HiFocus SlimJ, Cochlear Slim Straight, and MedEl Flex 24. For all samples tested:

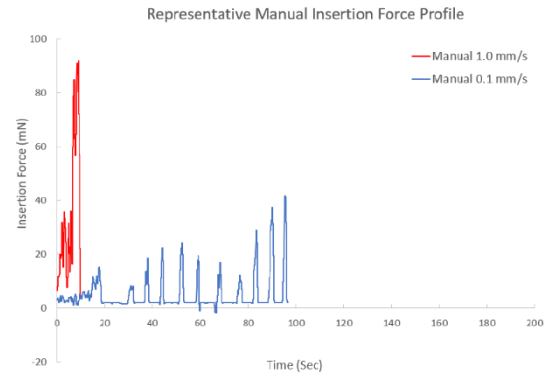
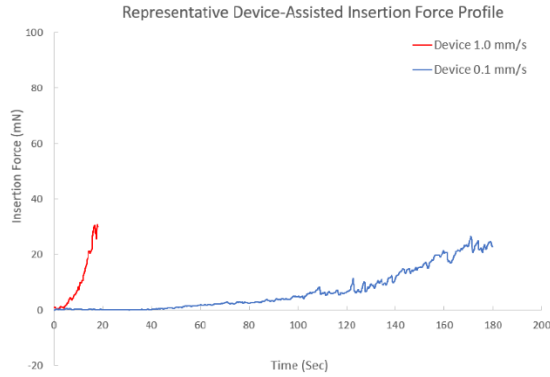
- insertion speed was verified to be within 20% of both 0.1 and 1 mm/s (lowest and highest) insertion rates
- maximum insertion force (with array) of <300mN was met at both the 0.1mm/s and 1mm/s insertion rates
- slip force specification of >80mN was met at both the 1mm/s and 0.1mm/s insertion rates
- maximum drive wheel pinch force of <5.6N
- drive head removal force (when decoupling array) of <100mN

Synthetic cochlea insertion force comparison (surgeon bench comparison testing):

Devices having undergone sterilization were tested with the following arrays: Advanced Bionics HiFocus SlimJ, Cochlear Slim Straight, and MedEl Flex 24. Both maximum insertion force and insertion force variation are lower on average for iotaSOFT versus manual insertion across multiple surgeons:

- The average of maximum insertion force for iotaSOFT assisted electrode array insertions were lower than average of maximum insertion force for manually inserted electrodes for both insertion rates, a 51% and 32% reduction at 0.1mm/s and 1mm/s, respectively.
- The average insertion force variation for iotaSOFT assisted electrode array insertions was 78% lower than the average insertion force for manually inserted electrode arrays at 0.1mm/s and 70% lower at 1mm/s.

Representative insertion force versus time profiles and summary tables of maximum insertion force and insertion force variation follow:



Maximum insertion force

Insertion Rate (mm/sec)	Insertion Method	Mean (mN)
0.1	iotaSOFT	(b) (4)
	Manual	
1.0	iotaSOFT	
	Manual	

Insertion force variation

Insertion Rate (mm/sec)	Insertion Method	Mean (mN/sec)
0.1	iotaSOFT	(b) (4)
	Manual	
1.0	iotaSOFT	
	Manual	

PERFORMANCE TESTING - CADAVER

Cadaveric comparison testing: iotaSOFT utilized and manual insertions by same surgeon in cadaver were compared. 16 surgeons implanted CIs in 16 cadaver heads. Each surgeon implanted an electrode array with one head using iotaSOFT on one side and manually contralaterally (same CI model, one device per side). MED-EL Flex 24 (n=6), AB HiFocus SlimJ (n=5), Cochlear Slim Straight (n=5) CI arrays were randomly assigned

and implanted per side by the 16 surgeons. During insertion, any array resistance, buckling, or incomplete insertion was noted. 3D x-ray was utilized to determine array intracochlear position. Histology was not assessed. Results across all surgeons and arrays in terms of array positioning summarized in table below:

	Scala Tympani Insertion	Scala Media Translocation	Scala Vestibuli Translocation	Tip Fold-Over	Insertion Angle (°)
Manual	7/16 (44%)	7/16 (43%)	2/16 (13%)	3/16 (19%)	309.98 ± 126.6 (N=16)
iotaSOFT	6/12* (50%)	5/12* (42%)	1/12* (8%)	1/12* (8%)	307.4 ± 95.9 (N=12)*

*Four samples were excluded post insertion from the comparative analysis due to the electrode inadvertently being removed from the cochlea following insertion either during electrical functional testing or tissue processing prior to scanning.

Results across all surgeons and arrays in terms of array positioning in the cochlea showed similar array placement in the cochlea (including cochlear translocations), tip foldover, and insertion angle.

Post insertion CI device impedance measurements when compared between manual insertion and iotaSOFT appeared unchanged and within normal limits.

Usability testing: Surgeon/Nurse teams (16 teams) performed cadaveric implantations (in 16 cadavers) with iotaSOFT in a simulated use environment (1 cadaver implanted by 1 team). MED-EL Flex24, AB HiFocus SlimJ, and the Cochlear Slim Straight devices were implanted, one device implanted by each team. Data collected: “was task successful?” Y/N responses (e.g., to “lock drive unit into base”), use errors, user comments, Likert-scale response to “able to secure base unit to skull.” Surgeons were freshly trained with the device prior to study participation and training decay time was included. Surgeon CI experience level ranged from 1 to 30+ years: approximately equal numbers of surgeons with less than 10 years, 10 to 20 years, and greater than 20 years. Between 10 and 180 implantations were performed manually in the year preceding this study, across all surgeons.

- Harms associated with use errors were deemed minor: prolonged operative/anesthesia time due to delay during surgery and prolonged operative/anesthesia time due to delay during set up. Mitigated with design changes to final De Novo device involving screws and screwdriver (revalidated) & training update.
- For all tasks, use errors deemed not to lead to serious patient harm. Any further mitigations deemed not to reduce the overall or individual risks.
- Data show that surgeons with nurse staff support can successfully use iotaSOFT in the hospital environment to aid in placement of the electrode array into the cochlea.

SUMMARY OF CLINICAL TESTING

Clinical testing in 21 subjects was performed by 3 surgeons with varying experience levels. CI models used: Cochlear Slim Straight (n=13), MED-EL Flex 28 (n=6), MED-EL Flex 24 (n=1), 1 AB HiFocus SlimJ. The principal investigator (PI) of the study was involved in the early device design phase and usability testing and completed 15 (of the 21) clinical cases; the other two study investigators were new users of the device and completed 2 cases and 4 cases respectively. The PI is a neurotologist with nearly 40 years experience who implanted ~75 CIs manually in the year prior to this study. The latter two surgeons implanted 25 to 30 CIs each in their careers prior to commencement of this study. Study subjects were aged 25 and older, and 21 iotaSOFT assisted implantations (in 21 subjects) were conducted.

As the IotaSOFT device is intended for cochlear implant array insertion, outcomes related to array insertion were collected and outcomes related to the cochlear implant system such as residual hearing measures, vestibular outcomes, and speech recognition metrics were not reported in the clinical study.

Summary of Results:

- There were no clinically significant patient safety or outcomes differences based on surgeon years of practice experience nor cochlear implantation experience.
- Electrode array impedance measures were within normal limits in all subjects as of 1 month follow up. Neural response telemetry (NRT) measurements were present in all subjects with normal cochlear anatomy¹ (n=20/21) at post-operative follow up.
- Adverse events following the proposed surgical protocol were generally as expected for cochlear implant procedures. (CSF leak occurred in one case when otologic drill was used for pilot hole, drill use is not according to iotaSOFT's instructions for use).
- Insertion time of the electrode array ranged from 57 sec to 6 min, 1 sec (mean 3 min 15 sec).
- Post-insertion cochlea view x-ray imaging of the electrode array was satisfactory on all insertions with normal cochlear anatomy¹ when utilizing the iotaSOFT Insertion System.

Pediatric Extrapolation

In this De Novo request, the clinical data summarized above was leveraged to support the benefit versus risk profile of the proposed device use in the pediatric sub-population of children 12 to 21 years old. This skull thickness and mastoid size are considered sufficiently developed for the iotaSOFT Insertion System to be used with patients aged 12 and older. The clinical data are thus considered leverageable to this pediatric sub-population.

¹ For one subject, NRT measurements were not obtained due to un-identified temporal bone fracture through the internal auditory canal.

LABELING

A surgical instructions for use is a necessary part of the labeling. This surgical instructions for use includes a list of compatible validated cochlear implants and a summary of supporting nonclinical and clinical performance data.

The contraindications identified in the iotaSOFT labeling contribute to the defined indications for use for the iotaSOFT. In accordance with 21 CFR 807.81(a)(3), FDA has determined that removal or modification of any of the contraindications will require submission of a premarket notification [510(k)], which includes non-clinical performance testing to demonstrate that intended users can use the device as intended with compatible cochlear implants, or rationale for omission of any testing (e.g., applicable data from a comparable model of cochlear implant).

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of a powered insertion system for a cochlear implant electrode array and the measures necessary to mitigate these risks.

Identified Risks to Health	Mitigation Measures
Risks to health relating to device interface with patient anatomy, including: <ul style="list-style-type: none">• 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: <ul style="list-style-type: none">• 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

SPECIAL CONTROLS

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.

BENEFIT-RISK DETERMINATION

CI manufacturer surgical guides recommendations vary. They may include discussion of speed of insertion and insertion forces and recommended instrumentation. Insertion utilizing a powered insertion device incorporates a hybrid approach. Utilization of the iotaSOFT device should be performed in consideration of the CI surgical instructions. Stabilized, steady, and slow insertions are recognized in the cochlear implant industry recommended surgical practices and academic literature recognizes these insertions as surgical approaches which decrease the risk of additional hearing loss or vestibular symptoms from inherently uncontrolled, variable, and excessively forceful insertions.^{1,2,3,4,5,6,7}

The iotaSOFT Insertion System stabilizes the electrode and permits slower constant motion (down to 0.1mm/sec insertion speed) and provides a more controlled insertion than is possible with manual, human capabilities. A study by Kesler et al. found that the lower limit of a manual, constant forward insertion motion by a CI surgeon to be a speed of 0.87 mm/sec.⁸ Lower maximum insertion force and lower insertion force variation were demonstrated for iotaSOFT versus manual insertion in synthetic cochlear model testing. Additionally, iotaSOFT holds and stabilizes the electrode during insertion to free up the surgeon's hand to guide a cochlear implant electrode array with manual tools. This design aspect of iotaSOFT attempts to reduce the risk of unwanted movement of the electrode array such as tremor or inadvertent manual surgeon movements. However, iotaSOFT versus manual insertions were similar per comparative cadaveric assessment in terms of array placement in the cochlea (including cochlear translocations), tip foldover, and insertion angle. Therefore, the benefits that were observed preclinically for iotaSOFT were restricted to more controlled insertion and lower insertion forces (and insertion force variation) than manual insertion.

Considering the clinical performance testing of 21 iotaSOFT implantations by 3 physicians, as of 1-month post activation, electrode impedances and neural telemetry measures were considered normal. Adverse events following the proposed surgical protocol were generally as expected for cochlear implant surgeries² and as expected when considered relative to manual cochlear implantation, e.g., there were no vestibular related adverse events outside of the mild and

² CSF leak occurred in one case when otologic drill was used for pilot hole (drill use is not according to iotaSOFT's instructions for use).

temporary symptoms as reported in cochlear implantations, in general. The following limitations are associated with the clinical study:

- Direct comparison data to manual insertions was not included in the scope of the study.
- Preservation of residual hearing was not within the scope of this clinical confirmatory study and 1-month postoperative hearing threshold data were not reported.
- Clinical study endpoint interval was at 1-month, postoperative; therefore, there was no long-term data provided.

Direct clinical benefit was not observed in the clinical and cadaveric studies of powered insertion as compared to manual insertion, and therefore, uncertainty exists in terms of the actual clinical benefit of powered insertion. However, the clinical confirmatory study measures of safety and effectiveness did indicate patient clinical performance using iotaSOFT for electrode array insertion was as expected and consistent with that seen at 1-month followup with manual insertions.

Risks associated with the use of iotaSOFT can be considered mitigated with surgeon training and labeling for indicated patients (12 years and older) for the 4 tested and validated cochlear implant arrays: Cochlear Slim Straight, MED-EL Flex 28, MED-EL Flex 24, Advanced Bionics HiFocus SlimJ. When used as intended, the risks due to use of iotaSOFT appeared to be no greater in severity or prevalence than risks associated with manual insertion.

In conclusion, the benefit/risk profile for the iotaSOFT Insertion System is considered favorable for the following reasons:

- Regarding clinical risk, adverse events/unmitigated risks related to the IotaSOFT insertion device use were not observed in the clinical and usability studies.
- As evidenced by benchtop performance characterizations, the iotaSOFT permits slower, more controlled insertions with a reduction in both maximum insertion force and insertion force variation of cochlear implant arrays versus manual insertion.
- The benefit of the device design related to slow, controlled insertion and the potential for reduced intracochlear trauma is supported by cochlear implant industry recommended surgical practices and academic literature.

References:

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Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

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 probable benefits outweigh the probable risks for the iotaSOFT Insertion System. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the iotaSOFT Insertion System is granted and the device is classified as follows:

Product Code: QQH
Device Type: Powered insertion system for a cochlear implant electrode array
Regulation Number: 21 CFR 874.4450
Class: II