



Food and Drug Administration
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August 19, 2016

Codman & Shurtleff, Inc.
Megan Palumbo
Senior Regulatory Affairs Specialist
325 Paramount Dr.
Raynham, Massachusetts 02767

Re: K153347

Trade/Device Name: Codman Microsensor Basic Kit, Codman Microsensor Plastic Skull Bolt Kit, Codman Microsensor Ventricular Catheter Kit With Tuohy-borst Adapter, Codman Microsensor Metal Skull Bolt Kit, Codman Microsensor Ventricular Catheter Kit

Regulation Number: 21 CFR 882.1620

Regulation Name: Intracranial Pressure Monitoring Device

Regulatory Class: Class II

Product Code: GWM

Dated: July 19, 2016

Received: July 20, 2016

Dear Ms. Palumbo:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

William J.
Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS,
ou=NIH, ou=People,
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Date: 2016.08.19 11:47:11 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K153347

Device Name

Codman® Microsensor: 62-6631 Microsensor Basic Kit, 62-6632 Microsensor Plastic Skull Bolt Kit, 62-6633 Microsensor Ventricular Catheter Kit with Tuohy-Borst Adapter, 62-6638 Microsensor Metal Skull Bolt Kit, and 62-6653 Microsensor Ventricular Catheter Kit

Indications for Use (Describe)

62-6631 Codman Microsensor Basic Kit:

Use of the CODMAN MICROSENSOR Basic Kit is indicated when direct ICP monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications only.

62-6632 and 62-6638 Codman Microsensor Skull Bolt Kit (Plastic and Metal):

Use of the CODMAN MICROSENSOR Plastic/Metal Skull Bolt Kit is indicated when direct intracranial pressure (ICP) monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications.

62-6633 Codman Microsensor Catheter Kit and

62-6653 Codman Microsensor Ventricular Catheter Kit with Tuohy-Borst Adapter:

Use of the Ventricular Catheter Kit is indicated when direct intraventricular pressure monitoring is required. The kit is indicated for use in ICP monitoring and cerebrospinal fluid (CSF) drainage applications.

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.

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510(k) SUMMARY**Codman® Microsensor Kits**

Date Prepared: November 13, 2015

Company Name: Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767

Contact Person: Megan Palumbo, Pharm D
Senior Regulatory Affairs Specialist
Telephone Number: (508) 828-3571
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Device Proprietary Name: Codman® Microsensor Kits

Device Common Name: Intracranial Pressure Transducer

Classification Name: Intracranial Pressure Monitoring Devices

Device Classification: Class II (21 CFR 882.1620)

Product Code: GWM

Type of 510(k) Submission: Traditional 510(k)

Basis for Submission: MR Labeling and Material Changes

Predicate Device(s): K914479 Codman® Intracranial Pressure Transducer
K974088 Codman® Intracranial Bolt (reference device)
K991222 Codman® Microsensor Ventricular Catheter Kit
(reference device)

Device Description

The Microsensor monitors intracranial pressure (ICP) through either a stand-alone probe, or a probe coupled with an EVD catheter, and is intended to be used in conjunction with the Codman ICP Express (product code 82-6635) neuromonitoring platform products. The ICP Express and Codman Microsensor are intended for use in Intensive Care Units (ICUs). The Microsensor converts the pressure signal to a voltage signal. The monitor provides power to the Microsensor, interprets the voltage signal from the Microsensor, and displays the corresponding pressure measurements taken by the Codman Microsensor during a patient's

treatment and during patient transport. There is no change to the Codman ICP Express monitor as a result of the probe modifications described in this submission.

The Codman Microsensor probe contains a small, thin and delicate pressure sensor used to measure the intracranial pressure. The sensing element uses a strain gauge located at the tip of the probe. The sensing element is protected by a titanium housing and is exposed to the environment via a silicone membrane. The sensor is connected via wires to a plastic connector housing, and the wires are snaked through a nylon catheter. The connector housing includes a compensation/calibration passive circuit on a Printed Circuit Board and has an electrical connector to attach the ICP Express monitoring box.

The Codman Microsensor Kits include components needed to facilitate the surgical implantation of the ICP Microsensor. The components that will be included with the proposed Codman Microsensor are currently cleared devices, and are identical to the components currently packaged within the current Codman Microsensor kits (i.e. via this 510k, there are no changes being made to the kit components, only the Microsensor is being updated). Each component and their function are described in the Description section of the Instructions for Use for each kit.

Indications for Use

Table 2 describes the Indications for Use statement for each of the 5 proposed Codman Microsensor product codes:

Table 2. Codman Microsensor Kit Indications for Use		
Device Description	Proposed Product Code	Indications for Use
Codman Microsensor Basic Kit	62-6631	Use of the CODMAN MICROSENSOR Basic Kit is indicated when direct ICP monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications only.
Codman Microsensor Skull Bolt Kit (Plastic and Metal)	62-6632 62-6638	Use of the CODMAN MICROSENSOR Plastic/Metal Skull Bolt Kit is indicated when direct intracranial pressure (ICP) monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications.
Codman Microsensor Catheter Kit & Codman Microsensor Ventricular Catheter Kit with Tuohy-Borst Adapter	62-6633 62-6653	Use of the Ventricular Catheter Kit is indicated when direct intraventricular pressure monitoring is required. The kit is indicated for use in ICP monitoring and cerebrospinal fluid (CSF) drainage applications.

Comparison to Predicate Device

Compared to the predicate device, the proposed Codman Microsensor Kit includes the modifications listed in **Table 3 and 3A**.

Table 3. Comparison of Predicate and Proposed Codman Microsensor Kits		
Characteristic	Predicate Codman Microsensor Kit (K914479)	Proposed Codman Microsensor Kit (This Submission)
FDA Product Code	GWM	Same as predicate
Classification	21 CFR 882.1620	Same as predicate
Classification Name	Device, Monitoring, Intracranial Pressure	Same as predicate
Indication for Use	<p>82-6631, 82-6632 & 82-6638 Indicated when direct ICP monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications only.</p> <p>82-6633, 82-6653 Indicated when direct intraventricular pressure monitoring is required. The kit is indicated for use in ICP monitoring and cerebrospinal fluid (CSF) drainage applications.</p>	<p>Same as predicate: 62-6631, 62-6632 & 62-6638 Indicated when direct ICP monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications only.</p> <p>62-6633, 62-6653 Indicated when direct intraventricular pressure monitoring is required. The kit is indicated for use in ICP monitoring and cerebrospinal fluid (CSF) drainage applications.</p>
Contraindications	See Table 3A	See Table 3A
Device Materials		
Printed Circuit Board (PCB) inside plastic connector housing	PCB Material: FR4 PCB Solder Mask Color: Green PCB Finish: Leaded	<i>ROHS Compliant:</i> PCB Material: FR-370HR PCB Solder Mask Color: Blue PCB Finish: Lead-Free
Solder Wire	Solder Wire, .015" K100LD "275"	<i>ROHS Compliant:</i> Lead-free Solder Wire, #66/275 K100LD, 0.015"
Solder Wire	Solder Wire, .031" SN63PB37 RA CORE	<i>ROHS Compliant:</i> Lead-Free Solder Wire, #66/275 K100LD, 0.031"
Thru-hole resistor located inside plastic connector	METAL FILM,RN55C/D/E	<i>ROHS Compliant:</i> METAL FILM,CMF55,SERIES,ROHS
Epoxy Glue	Armstrong A-2/H-20	Loctite M-121HP
Catheter 100cm tubing	Besno Nylon 11, White	Besno Nylon 11, 2.5% Yellow
Sensor Top Label for the plastic connector housing.	Material: #30 High Gloss White Paper Adhesive: 3M 320/320 NR Acrylic Adhesive Back	Same as Predicate Sensor Bottom Label: Material: 70# C1S Digital Top Coated litho paper, 3.7-mil (DO7000) Adhesive: 2.0-mil acrylic adhesive (JDC item 2369sl) Laminate: 1.5-mil polypropylene (STA item 1206)
Sensor Bottom Label on plastic connector housing	Material: 70# C1S Digital Top Coated litho paper, 3.7-mil (DO7000) Adhesive: 2.0-mil acrylic adhesive (JDC item 2369sl) Laminate: 1.5-mil polypropylene (STA item 1206)	Same as predicate

Table 3.		
Comparison of Predicate and Proposed Codman Microsensor Kits		
Characteristic	Predicate Codman Microsensor Kit (K914479)	Proposed Codman Microsensor Kit (This Submission)
Catheter Strain Relief	Clear Silicone	Same as predicate
Titanium Case	Titanium Grade 2	Same as predicate
Silicone Membrane	RTV-112	Same as predicate
Packaging Materials		
Pouch (62-6631, 62-6632, 62-6638)	TPT 0260 Coated TYVEK sealed to TPF 0501A film.	Same as predicate
Unit Box (62-6631, 62-6632, 62-6638)	Performa White 350 g/m ²	Same as predicate
Blister Lid (62-6633)	HCW-CR27 Coated Tyvek	Same as predicate
Blister Tray (62-6633)	PETG	Same as predicate
Unit Box (62-6633)	Solid bleached sulfate 20pt paper board	Same as predicate
Pouch (62-6653)	TPT 0260 Coated TYVEK sealed to TPF 0501A film	Same as predicate
Unit Box (62-6653)	Solid bleached sulfate 20pt paper board	Same as predicate
Device Characteristics		
MRI claim	None	1.5T and 3T Conditional
Sterilization	Ethylene Oxide	Same as predicate
Shelf Life	5 years	2 year
Energy Modality	5 volts DC when connected to the ICP monitoring device	Same as predicate
Micro sensor Dimensions	Length: 100cm nominal Tip diameter: 1.3mm max Tubing diameter: 0.8mm max Catheter length (ventricular kit): 38cm nominal Catheter diameter (ventricular kit): 3.5mm max	Same as predicate
Sensing Element	Strain gauge silicon microchip	Same as predicate
Functional Pressure Range	-50mmHg to 250mmHg	Same as predicate
Functional Over Pressure Range Without Damage	-700mmHg to 1250mmHg	Same as predicate
Input/Output Impedance	1000 ohms nominal	Same as predicate
Output Signal (sensitivity)	5uV/V/mmHg	Same as predicate
Zero Drift	No greater than 5mmHg/7days	No greater than 5mmHg over 30 days

Table 3A.		
Comparison of Predicate and Proposed Codman Microsensor Kits		
Characteristic	Predicate Codman Microsensor Kit (K914479)	Proposed Codman Microsensor Kit (This Submission)
Labeling		
Indication for Use	82-6631, 82-6632 & 82-6638 Indicated when direct ICP monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications only. 82-6633, 82-6653	Same as predicate: 62-6631, 62-6632 & 62-6638 Indicated when direct ICP monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications only. 62-6633, 62-6653

Table 3A.		
Comparison of Predicate and Proposed Codman Microsensor Kits		
Characteristic	Predicate Codman Microsensor Kit (K914479)	Proposed Codman Microsensor Kit (This Submission)
	Indicated when direct intraventricular pressure monitoring is required. The kit is indicated for use in ICP monitoring and cerebrospinal fluid (CSF) drainage applications.	Indicated when direct intraventricular pressure monitoring is required. The kit is indicated for use in ICP monitoring and cerebrospinal fluid (CSF) drainage applications.
Contraindications <i>(differences are italicized)</i>	82-6631: <ul style="list-style-type: none"> • This kit is not designed, sold or intended for any use except as indicated • This kit is not designed, sold or intended for use as a therapeutic device • <i>Compatibility of implantable catheter-tipped pressure transducers with magnetic resonance imaging (MRI) has not been determined.</i> 	62-6631: <ul style="list-style-type: none"> • This kit is not designed, sold or intended for any use except as indicated • This kit is not designed, sold or intended for use as a therapeutic device
	82-6632: <ul style="list-style-type: none"> • Insertion of the skull bolt is contraindicated in children under one year of age. • This kit is not designed, sold, or intended for any use except as indicated. • This kit is not designed, sold, or intended for use as a therapeutic device. • <i>Compatibility of implantable catheter-tipped pressure transducers with magnetic resonance imaging (MRI) has not been determined.</i> 	62-6632: <ul style="list-style-type: none"> • Insertion of the skull bolt is contraindicated in children less than one year of age. • This kit is not designed, sold, or intended for any use except as indicated. • This kit is not designed, sold, or intended for use as a therapeutic device.
	82-6633: <ul style="list-style-type: none"> • <i>Monitoring of intracranial pressure through the use of ventriculostomy techniques may be contraindicated (e.g., with conditions such as encephalitis, brain swelling secondary to trauma, diffuse encephalopathies, and Reye's syndrome).</i> Ventriculostomy is contraindicated in patients with a coagulopathy. • Use of the CODMAN MICROSENSOR Catheter Kit is contraindicated in children under one year of age. • This device is not designed, sold, or intended for any use except as indicated. • <i>This device is not designed, sold, or intended for use as a therapeutic device.</i> • <i>Compatibility of implantable catheter-tipped pressure transducers with magnetic resonance imaging (MRI) has not been determined.</i> 	62-6633: <ul style="list-style-type: none"> • Ventriculostomy is contraindicated in patients with coagulopathy <i>or active infection in the area of the catheter.</i> • Use of the Ventricular Catheter Kit is contraindicated in children less than one year of age. • This kit is not designed, sold, or intended for any use except as indicated.
	82-6638: <ul style="list-style-type: none"> • <i>Insertion</i> of the skull bolt is contraindicated in children under one year of age. • This device is not designed, sold, or intended for any use except as indicated. • This kit is not designed, sold, or intended for use as a therapeutic device. 	62-6638: <ul style="list-style-type: none"> • Use of the skull bolt is contraindicated in children less than one year of age. • This kit is not designed, sold, or intended for any use except as indicated. • This kit is not designed, sold, or intended for use as a therapeutic device.

Characteristic	Predicate Codman Microsensor Kit (K914479)	Proposed Codman Microsensor Kit (This Submission)
	<ul style="list-style-type: none"> Compatibility of implantable catheter-tipped pressure transducers with magnetic resonance imaging (MRI) has not been determined. 	
	82-6653: <ul style="list-style-type: none"> Ventriculostomy is contraindicated in patients with coagulopathy or active infection in the area of the catheter. Use of the CODMAN Ventricular Catheter Kit is contraindicated in children under one year of age. 	62-6653: <ul style="list-style-type: none"> Ventriculostomy is contraindicated in patients with coagulopathy or active infection in the area of the catheter. Use of the Ventricular Catheter Kit is contraindicated in children less than one year of age. <i>This kit is not designed, sold, or intended for any use except as indicated.</i>
MRI claim	None	1.5T and 3T Conditional
Shelf Life	5 years	2 year

Performance Data

The following performance data are provided in support of the substantial equivalence determination:

Bench Testing

Bench testing on the proposed device, the Codman Microsensor, included the Design Verification and Validation tests listed in **Table 4**:

Test	Test Method Summary	Results
Long Term Accuracy	The purpose of this test is to confirm the pressure accuracy, linearity, hysteresis, and sensitivity of the device over time.	PASS:
Long Term Drift	The purpose of this test is to confirm the drift characteristic of the device over time. The report also evaluates if there is any fluid ingress into the probe's sensing element.	PASS:
Temperature Sensitivity	The purpose of this test is to confirm the sensitivity of the pressure output to temperature changes.	PASS:
Seal Integrity	The purpose of this test is to confirm that there is no fluid ingress into the probe's sensing element. Seal integrity refers to the mechanical barrier that prevents fluids to contact the electrical components of the pressure probe sensing elements.	PASS:
Bond Strength	The purpose of this test is to confirm the mechanical strength of the device and determine if it meets the pull force requirements.	PASS:
Flexibility	The purpose of this test is to confirm the flexibility of the device (coiling) and determine if it affects its ability to measure pressure.	PASS:
Kink	The purpose of this test is to confirm the kink resistance of the device and determine if it affects its ability to measure pressure.	PASS:
Connector Cycles and Impedance	The purpose of this test is to confirm the reliability of the device's connector by measuring the input and output impedance after a connect/ disconnect simulation and to confirm that the input and output impedance values meet specifications.	PASS:
Zero Offset	The purpose of this test is to confirm that initial zero offset of the pressure sensor is within the specified value.	PASS:
Heat Transfer	The purpose of this test is to confirm that the heat dissipation of the implantable portion of the device does not exceed the maximum temperature recommended in ANSI AAMI NS28(1988)-R(2010).	PASS:
Frequency Response	The purpose of this test is to confirm the frequency response (i.e., bandwidth) of the device	PASS:
Environmental	The purpose of this test is to confirm that the device are not affected by transportation conditions (e.g., vibration and drops), that it can be stored at the specified temperature and humidity levels, and that it can operate within the expected environmental conditions including temperature, humidity and altitude.	PASS:

Test	Test Method Summary	Results
Critical Dimensions	The purpose of this report is to confirm the physical dimensions of the device and confirm that the samples used for design verification testing meet the product drawing.	PASS:
MRI Compatibility	The purpose of this test is to confirm the functionality of the device before and after exposure to 1.5T MRI and 3T MRI.	PASS:
MRI Safety	Refer to Table 5	Refer to Table 5
Radiopacity	The purpose of this test is to confirm that the device has a radiopaque feature that can be detected in an X-ray image	PASS:
CT Scan Compatibility	The purpose of this test is to confirm the functionality of the device before and after a CT scan exposure	PASS:
Over Pressure	The purpose of this test is to confirm that the device can withstand extreme pressures without damage	PASS:
Calibration Stability	The purpose of this test is to confirm the sensitivity of the probe calibration to impacts to the device's housing	PASS:
MRI Safety	Refer to Table 5	Refer to Table 5
Sterilization	EO Residual Testing per ISO 10993-7:2008 (R) 2012	PASS:
Biocompatibility	Refer to Table 6 and 7	Refer to Table 6 and 7
ICP Express Compatibility	The purpose of this test is to confirm that the device will work as intended with the ICP Express Monitor	PASS:

Test results demonstrated that the acceptance criteria were met, therefore, the Codman Microsensor conforms to expected device performance and intended use. Results of verification and validation testing have demonstrated that the proposed Codman Microsensor is substantially equivalent to the predicate Codman Intracranial Pressure Transducer, and that the modifications do not impact the safety or effectiveness of the proposed device.

Magnetic Resonance (MR) Testing

The safety test requirements of the ASTM MR standards for the proposed Codman Microsensor have been met through testing. The Codman Microsensor is MR-Conditional at 1.5 and 3.0 Tesla per the following standards listed in **Table 5**.

Test	Test Method	Results
Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	ASTM F2503-13	PASS
Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	ASTM F2052-15	PASS
Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging	ASTM F2182-11a	PASS
Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants	ASTM F2119-07 (R2013)	PASS
Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment	ASTM F2213-06 (R2011)	PASS
Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	ISO 10974:2012	PASS

Biocompatibility Testing

The biocompatibility evaluations for the Codman Microsensor were conducted in accordance with the FDA Blue Book Memorandum #G95-1 *Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing* May 1, 1995, and International Standard ISO 10993-1 *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process* as recognized by FDA. In addition, information on the yellow colorant recommended by the FDA in the 2013 Draft Guidance on use of ISO 10993-1 was obtained and a toxicological risk assessment of the constituents of the yellow colorant formulation was conducted.

Codman Microsensor Probe Tip and Tubing

The Codman Microsensor Probe Tip and Tubing are considered an implant device with prolonged contact (>24, but ≤30 days) to bone and tissue. Biocompatibility testing was completed with passing results. The following tests listed in **Table 6** were conducted:

Table 6. Biocompatibility Tests Conducted – ICP Probe Tip and Tubing	
TEST	Result
In Vitro Cytotoxicity – ISO MEM Elution	Non-cytotoxic
Guinea Pig Sensitization – ISO Maximization	Non-sensitizing
Intracutaneous/Irritation Reactivity – ISO Intracutaneous in Rabbits	Non-irritating
Acute Systemic Toxicity – ISO Systemic Toxicity in Mice	Non-toxic
Material Mediated Pyrogenicity – USP Rabbit Pyrogen	Non-pyrogenic
ISO Muscle Implantation Study in Rabbits (4 weeks)	Non-irritant
In Vitro Ames Bacterial Reverse Mutation Assay	Non-mutagenic
In Vitro Mouse Lymphoma Mutagenicity Assay	Non-mutagenic
In Vivo Mouse Peripheral Blood Micronucleus Assay	Non-clastogenic
ISO Systemic Toxicity Study in Rats Following Subcutaneous Implantation (4 weeks)	Non-toxic and Non-irritating
USP Physicochemical Tests (Aqueous Extracts)	PASS
Subacute Toxicity Study to Assess the Tissue Response to Codman Neuro's RoHS ICP Probe in the Rabbit Brain	PASS
ASTM In Vitro Hemolysis	PASS

Codman Microsensor Electrical Housing

The Codman Microsensor Electrical Housing is considered a surface device with prolonged contact (>24, but ≤30 days) to skin. Biocompatibility testing was completed with passing results. The following tests listed in **Table 7** were conducted:

Table 7. Biocompatibility Tests Conducted – Electrical Housing Connector	
TEST	Result
In Vitro Cytotoxicity – ISO MEM Elution	Non-cytotoxic
Guinea Pig Sensitization – ISO Maximization	Non-sensitizing
Intracutaneous/Irritation Reactivity – ISO Intracutaneous in Rabbits	Non-irritating
USP Physicochemical Tests (Aqueous Extracts)	Met USP <661> limits (Pass)

Sterilization

The Codman Microsensor Kits are sterilized using Ethylene Oxide sterilization and were validated and audited to assure a Sterility Assurance Level (SAL) 10^{-6} .

Animal Studies

No animal studies were required, as appropriate verification of the modified device was achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing and the biocompatibility evaluation.

Clinical Studies

No clinical studies were required, as appropriate verification of the modified was achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing and the biocompatibility evaluation.

Statement of Substantial Equivalence

Based upon the design, function, materials, intended use, and the testing performed for this submission, it is concluded that the proposed Codman Microsensor Kits are substantially equivalent to the predicate Codman Microsensor Kits (K914479) and do not raise new issues of safety and effectiveness.