Section 6 – 510(k) Summary

510(k) Summary

Codman Electrosurgical Generator

K183526

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3. **Date Prepared**
   December 17th, 2018

4. **Device Identification**

Trade/Proprietary Name:	Codman Electrosurgical Generator
Common/Usual Name:	Electrosurgical Generator
Classification Name:	Electrosurgical, cutting & coagulation & accessories
Regulation Number:	21 CFR 878.4400
Product Code:	GEI
Device Class:	Class II
Classification Panel:	General and Plastic Surgery

5. **Legally Marketed Predicate Device**
   Sutter CURIS® RF Generator by Sutter Medizintechnik GmbH; K171869

6. Indication for Use Statement

The Generator is indicated for use for cutting and coagulation of soft tissue in neurosurgical procedures.

7. Device Description

The Codman Electrosurgical Generator is a compact source of high radiofrequency RF energy to be used with monopolar and bipolar instruments to cut and coagulate tissue during surgical procedures. This is achieved by the selection of electrosurgical accessories (e. g. monopolar or bipolar instruments), different operating modes and power levels on the front panel of the device. All selections are effected through pushbuttons and knobs. Indicator lights give the operator feedback on the status.

The power level for each mode is indicated by front-panel digital displays. During self-test or for error messages these digital displays also serve as indicators. Activation of output power is performed through an instrument's finger switch and/or a foot pedal.

The maximum power output of the device in CUT mode is 80 watts (at 600 Ohms load), and 80 watts in COAG mode (at 400 Ohms load). Operating frequency of the device is maintained at 4.0 MHz.

The device offers both monopolar and bipolar output wave forms. Both monopolar mode and bipolar mode offers one CUT and one COAG wave form, translating into a total of 4 operating modes for the user.

The Codman Electrosurgical Generator is packaged together with power cord and instruction manual. Typical accessories are a foot pedal with cable (part of this 510(k) submission) and appropriate monopolar and bipolar cables, electrodes and instruments, which are cleared and available separately.

The Codman Electrosurgical Generator is a prescription device.

8. Substantial Equivalence Discussion

The following table compares the Codman Electrosurgical Generator to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 6A – Comparison of Characteristics

Manufacturer	**Integra LifeSciences Corporation**	**Sutter Medizintechnik GmbH**
Trade Name	**Codman® Electrosurgical Generator (Subject Device)**	**CURIS® RF Generator (Predicate Device)**

Manufacturer	**Integra LifeSciences Corporation**	**Sutter Medizintechnik GmbH**
Trade Name	**Codman® Electrosurgical Generator** **(Subject Device)**	**CURIS® RF Generator** **(Predicate Device)**
510(k) Number	TBD	K171869
Product Code	GEI	GEI
Regulation Number	21 CFR 878.4400	21 CFR 878.4400
Regulation Name	Electrosurgical, cutting & coagulation & accessories	Electrosurgical, cutting & coagulation & accessories
Indications for Use	The Generator is indicated for use for cutting and coagulation of soft tissue in neurosurgical procedures.	Orthopedic, arthroscopic, spinal and **neurosurgical**: For **resection and coagulation of soft tissues** and hemostasis of blood vessels in orthopedic, arthroscopic, spinal and neurosurgical procedures For soft tissue resection and coagulation during arthroscopic surgical procedures of knee, shoulder, ankle, elbow, hip and wrist. **Cutting**: Snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment and turbinate shrinkage, skin incisions, biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags, blepharoplasty Blended Cutting and Coagulation: Snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment and turbinate shrinkage, skin tags, papilloma keloids, keratosis, verrucae, basal cell carcinoma, nevi, fistulas, epithelioma, cosmetic repairs, cysts, abscesses, development of skin flaps Hemostasis and nonablative Coagulation: Control of bleeding, epilation, teleangiectasia Bipolar: Pinpoint, precise coagulation, pinpoint hemostasis in any field (wet or dry), snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment and turbinate shrinkage

Manufacturer	**Integra LifeSciences Corporation**	**Sutter Medizintechnik GmbH**
Trade Name	**Codman® Electrosurgical Generator (Subject Device)**	**CURIS® RF Generator (Predicate Device)**
Material	Metal & plastics	Metal & plastics
Battery Operated	No	no
AC Powered	Yes	yes
Electrical Safety	IEC 60601-1 all applicable requirements met	IEC 60601-1 all applicable requirements met
Electromagnetic Compatibility	IEC 60601-1-2 all applicable requirements met	IEC 60601-1-2 all applicable requirements met
HF Electrical Safety	IEC 60601-2-2 all applicable requirements met	IEC 60601-2-2 all applicable requirements met

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Codman Electrosurgical Generator and in showing substantial equivalence to the predicate device that is subject to this 510(k) submission, Integra LifeSciences Corporation completed a number of non-clinical performance tests against applicable standards.

Table 6B – Performance Standards Testing Summary

Test		Pass / fail criteria	Results
1	Electrical safety	Compliance to IEC 60601-1:2005 + A1:2012; ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	Passed
2	Electrical safety	Compliance to IEC 60601-2-2:2017 (Generator) Compliance to IEC 60601-2-2:2009 (Foot Pedal)	Passed
3	Electromagnetic compatibility	Compliance to IEC 60601-1-2:2014	Passed
4	Risk Management	Compliance to ISO 14971:2007	Passed
5	Software Performance	Compliance to IEC 62304:2006	Passed

To demonstrate that the Codman Electrosurgical Generator meets all design specifications and performance requirements, nonclinical bench testing has been performed in accordance with the internal R&D process in compliance with the proposals and recommendations of FDA guidance: “Premarket Notification [510(k)] Submissions for Electrosurgical Devices for General Surgery” – Guidance for Industry and Food and Drug Administration Staff, August 15, 2016.

In particular, tests have been carried out with respect to the following subject areas:

- Electromagnetic Compatibility and Electrical Safety
- System Performance Testing
- Thermal effects on tissue
- Usability
- Transport simulation

Internal verification and validation testing confirms that product specifications are met which are equivalent to the predicate device in technological characteristics. The testing results support that the requirements for performance and electrical safety testing were met for the acceptance of the device. The Codman Electrosurgical Generator passed all testing and supports the claims of substantial equivalence to the predicate device.

10. Statement of Substantial Equivalence

Based upon the intended use, design, operating principles, patient/user interface, comparison to the predicate device, and testing conducted, it is concluded that the subject device, Codman Electrosurgical Generator, is substantially equivalent to the predicate device, Sutter CURIS® RF Generator (K171869), and therefore does not raise different questions of safety and effectiveness.