November 20, 2020

Integra LifeSciences Corporation
Alyssa Woodcock
Regulatory Affairs Product Manager
11 Cabot Boulevard
Mansfield, Massachusetts 02048

Re: K193346
Trade/Device Name: Codman Surgical Pattie & Strip
Regulation Number: 21 CFR 882.4700
Regulation Name: Neurosurgical Paddie
Regulatory Class: Class II
Product Code: HBA
Dated: October 19, 2020
Received: October 21, 2020

Dear Alyssa Woodcock:

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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193346

Device Name
Codman Surgical Patties and Strips

Indications for Use *(Describe)*
The surgical patties and surgical strips are indicated for the use in protection of tissue, including brain and other tissues of the central nervous system, during surgery.

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

Date: **November 20, 2020**

Submission number: **K193346**

I. Submitter

Integra LifeSciences Corporation
11 Cabot Boulevard
Mansfield, MA 02048

Contact: Alyssa Woodcock
Phone: (508) 615-7426

Establishment Registation: 3014334038

II. Device

Device Proprietary Name	Codman® Surgical Pattie and Strip
Common Name	Pattie and Strip
Classification Name	Neurosurgical Paddie (21 CFR 882.4700)
Regulatory Classification	II
Product Code	HBA
Review Panel	Neurology

III. Predicate Device

The predicate device for this submission is the Codman® Surgical Pattie (K880402), which was cleared on March 2, 1988.

IV. Device Description

The Codman Surgical Patties and Strips are single use, sterile devices indicated for the use in protection of tissue, including brain and other tissues of the central nervous system, during surgery.

The Surgical Patties are comprised of 3 main components: Cottonoid Material, String and X-ray detectable monofilament.

The Strips are comprised of 2 main parts: Cottonoid Material and X-ray detectable monofilament.

V. Indications for Use

The Surgical Patties and Surgical Strips are indicated for the use in protection of tissue, including brain and other tissues of the central nervous system, during surgery.

VI. Comparison to Predicate Device

The proposed Codman Surgical Patties & Strips are identical to the currently marketed Codman Surgical Patties and Strips (K880402) with the exception that this submission proposes to use a non-phthalate PVC Resin instead of PVC Resin containing phthalates for the x-ray detectable monofilament affixed to the Surgical Patties and Strips.

The indications for use, design, principle of operation, manufacturing process, clinical utility, packaging, and sterilization will remain unchanged and identical to the predicate device.

Accelerated shelf-life testing has been completed to for 2 years and will be updated to 5 years once testing has been completed. The current marketed Codman Surgical Patties and Strips (K880402) has a 5-year shelf-life; therefore, the proposed Surgical Patties and Strips will be tested to a 5-year shelf-life.

Comparison of the Predicate and Subject Device			
	Predicate Device: Codman Sugical Patties & Strips (K880402)	**Subject Device: Codman Patties & Strips (This Submission)**	**Difference and Justification**
FDA Product Code	HBA	Same as predicate	No difference
Classification	Class II - 21 CFR 882.4700	Same as predicate	No difference
Classification Name	Neurosurgical Paddie	Same as predicate	No difference
Intended Use	The surgical patties and surgical strips are indicated for the use in protection of tissue, including brain and other tissues of the central nervous system, during surgery.	Same as predicate	No difference
Single Use	Yes	Same as predicate	No difference
Radiopaque	Yes	Same as predicate	No difference
Material	Pattie/Strip: Cottonoid String: braided, textured Polyester X-ray Monofilament: Phthalate containing PVC material for x-ray detection	Same materials as predicate except a similar PVC material without phthalate will be used for the x-ray monofilament.	The testing (i.e. Visual Inspection, Functional, Mechanical, Shelf Life, Sterility and Biocompatibility testing) performed verified that the performance and safety of the proposed device is substantially equivalent to that of the predicate device and does not introduce any new questions of safety and effectiveness.
Sterile	Yes, ETO Sterilized	Same as predicate	No difference
Sterility Assurance Level (SAL)	10^{-6}	Same as predicate	No difference

Comparison of the Predicate and Subject Device			
	Predicate Device: Codman Sugical Patties & Strips (K880402)	**Subject Device: Codman Patties & Strips (This Submission)**	**Difference and Justification**
Packaging	**Patties:** Packaging using Form Fill Seal to create Sterile Barrier, placed in a Pouch with Tyvek Lid, (Pouch – plastic film, Lid – Tyvek) and then placed in a Carton and Labeled (Carton – Single walled cardboard) **Strips:** Packaged using Ceratek Pouch Sealer to create Sterile Barrier, placed in a Pouch with Tyvek for sterilization (Pouch – Plastic Film and Tyvek) and then placed in Carton and Labeled (Carton – Single walled cardboard)	Same as predicate	No difference
Shelf Life	5 years	2 years	The 2-year shelf life does not raise new questions of safety and effectiveness because testing was performed per FDA recognized standard, ASTM F640 and the results met the acceptance criteria.

VII. Performance Data

There were no changes made that affect the Codman Surgical Patties and Strips indications for use, principle of operation, manufacturing process, clinical utility, packaging, shelf life and sterilization. The difference between the predicate and proposed device is the use of a non-phthalate PVC Resin instead of PVC Resin that contains phthalates for the construction of the x-ray detectable monofilament. In addition, the proposed device has been tested to 2-year shelf life and testing is ongoing to 5-year shelf life to match the currently marketed Codman Surgical Patties and Strips shelf life of 5 years. Below is a summary of the testing performed to support the substantial equivalence between the proposed and predicate devices:

Test	Test Method Summary	Results
Visual Inspection (Patties)	Evaluated the following pattie specifications: 1. String and X-ray isolation 2. X-ray weld strength 3. X-ray flash	All samples passed the acceptance criteria demonstrating that the proposed patties meet the same performance specification as the predicate device. This supports that

		the performance of the proposed device with a non-phthalate PVC Resin is substantially equivalent to that of the predicate device.
Visual Inspection (Strips)	Evaluated the following parameters of the strips: 1. X-ray weld strength 2. X-ray flash	All samples passed the acceptance criteria demonstrating that the proposed strips meet the same specifications as the predicate strips. This supports that the performance of the proposed device with a non-phthalate PVC Resin is substantially equivalent to that of the predicate device.
Radiopacity (Patties and Strips)	Evaluated the visibility of the finished good under X-ray per FDA recognized standard, ASTM F640-12	All samples passed the qualitative acceptance criteria. This supports that the performance of the proposed device with a non-phthalate PVC Resin is substantially equivalent to that of the predicate device.
Sterilization Validation (Cottonoid and X-ray Strip)	Testing was conducted to achieve a 10^{-6} sterility assurance level using the overkill process per FDA recognized standard, ISO 11135:2014 with a reference product load that included "worst case" product.	The test results met the EO/ECH residual and bioburden acceptance criteria and achieved a sterility assurance level of 10^{-6}. The acceptance criteria is the same as the predicate device, supporting substantial equivalence between the proposed and predicate devices.
Shelf-Life (2-years)	The following test methods were used to evaluate the product after 2-years accelerated aging: • X-ray shall not proture • ASTM F640 • X-ray shall exhibit adequate adherence • X-ray shall not overlap string.	All product tested passed the acceptance criteria. The proposed device has been tested to 2-year shelf life which is within the current shelf life claim for the predicate device.
Biocompatibility Testing		
Cytotoxicity Testing	Determine the potential of a test article extract to cause cytotoxicity per ISO 10993-5 Tests for in vitro cytotoxicity (Less than or equal to grade 2 reactivity on the 0 to 4 reactivity scale)	All product tested passed the acceptance criteria demonstrating that the device is biocompatible and therefore is substantially equivalent to the predicate device.
ISO Intracutaneous Study in Rabbits	Evaluate the local dermal irritation of a test article extract following intracutaneous injection in rabbits per ISO 10993-10 Tests for irritation and skin sensitization (Difference between test article extract overall mean score and control group score is 1.0 or less)	All product tested passed the acceptance criteria demonstrating that the device is biocompatible and therefore is substantially equivalent to the predicate device.
USP Rabbit Pyrogen Study, Material Mediated	Determine whether an extract of the test article induced a pyrogenic response following intravenous injection in rabbits per ISO 10993-11 Tests for Systemic Toxicity (No single animal shows a rise of $0.5^{\circ}C$ above its baseline temperature)	All product tested passed the acceptance criteria demonstrating that the device is biocompatible and therefore is substantially equivalent to the predicate device.
ISO Acute Systemic Toxicity Study in Mice	Evaluate the acute systemic toxicity of a test article extract following injection in mice per ISO 10993-11 Tests for Systemic Toxicity (No single animal treated with the individual test extract exhibits a significantly greater reaction	All product tested passed the acceptance criteria demonstrating that the device is biocompatible and therefore is substantially equivalent to the predicate device.

	than the control animals: no more than two animal deaths; no abnormal behavior such as convulsions or prostration occurs in two or more animals; no final body weight loss greater than 10% occurred in three or more animals)	
ISO Guinea Pig Maximization Sensitization Test	Evaluate the potential of the test article to cause delayed dermal contact sensitization in the guinea pig maximization test per ISO 10993-10 Tests for irritation and skin sensitization (A grade of 0 on a patch test reaction scale of 0-3)	All product tested passed the acceptance criteria demonstrating that the device is biocompatible and therefore is substantially equivalent to the predicate device.
ASTM Hemolysis Study	Evaluate the potential to cause hemolysis. This study was conducted based on ASTM F756 and ISO 10993-4 (Acceptance criteria of hemolytic index for the test article extract to be 0.1% and non-hemolytic.)	All product tested passed the acceptance criteria demonstrating that the device is biocompatible and therefore is substantially equivalent to the predicate device.

Bench Testing

Visual Inspection, Functional Testing (Radiopacity Testing), Mechanical Testing (Weld Strength), Shelf Life testing, Sterility testing and Biocompatibility testing were performed to verify that the performance of the proposed device with a non-phthalate PVC Resin is substantially equivalent to that of the current device, which uses PVC Resin containing phthalates).

Animal Studies

No animal studies were performed as appropriate verification and validation of the subject device was achieved based on the comparison to the predicate device and from the results of the bench, sterilization, shelf-life and biocompatibility testing.

Clinical Studies

No clinical studies were performed as appropriate verification and validation of the subject device was achieved based on the comparison to the predicate device and from the results of the bench, sterilization, shelf-life and biocompatibility testing.

VIII. Conclusion

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 Surgical Pattie and Strip is substantially equivalent to the predicate device.