January 28, 2022

Synthes (USA) Products, LLC
Doug Steinberger
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K212943
Trade/Device Name: SYNTHECEL Dura Repair
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: December 22, 2021
Received: December 27, 2021

Dear Doug Steinberger:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212943

Device Name
SYNTHECEL Dura Repair

Indications for Use *(Describe)*
SYNTHECEL Dura Repair is indicated as a dura replacement for the repair of dura mater in adults.

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 – SYNTHECEL Dura Repair

Date Prepared	January 28, 2022
Submitter	Synthes (USA) Products LLC 1230 Wilson Drive West Chester, PA 19380
Contact	Doug Steinberger (419) 307-0674 (phone) DSTEINB1@ITS.JNJ.COM
Device Name	SYNTHECEL® Dura Repair
Regulation Number	21 CFR 882.5910
Device Class	2
Product Code(s)	GXQ
Predicate Devices	SYNTHECEL® Dura Replacement Devices (K113071) SYNTHECEL® Dura Repair (K131792)
Reference Device	Durepair Dura Regeneration Matrix (K161370)
Device Description	SYNTHECEL® Dura Repair is composed of biosynthesized cellulose and water with a unique construction of non-woven, interconnected cellulose fibers. SYNTHECEL® Dura Repair functions as a mechanical layer which protects and repairs the dural defect while preventing further CSF leakage. SYNTHECEL® Dura Repair is immunologically inert and has demonstrated minimal foreign body response. It is non-resorbable.
Indications for Use	SYNTHECEL® Dura Repair is indicated as a dura replacement for the repair of dura mater in adults.
Technological Characteristics	The SYNTHECEL® Dura Repair is equivalent to the predicate devices (K113071 & K131792) in terms of intended use. Both are designed for dura replacement for the repair of dura mater. The material, physical properties, resorbability, and mechanical performance are identical to the predicate devices. This submission covers a larger size offering that is dimensionally different in length and width compared to predicates but is similar in length and width to the largest Durepair product (K161370) as a reference.
Clinical Performance Data	No new clinical performance data were collected in support of this submission. Clinical data were previously collected to evaluate the safety and effectiveness of the SYNTHECEL® Dura Replacement Devices (K113071) as compared to the Control.
Non-Clinical Performance Data	Mechanical testing data was collected to support substantial equivalence of SYNTHECEL® Dura Repair to predicate devices. Burst strength and suture pull-out strength were tested and SYNTHECEL® Dura Repair was demonstrated to be substantially equivalent to predicate devices. Biocompatibility testing according to standards set forth in ISO 10993-1 demonstrated that the material is non-irritating, non-sensitizing, non-mutagenic, non-cytotoxic, non-hemolytic, non-pyrogenic and of appropriate pH. Device packaging was justified via prior shelf-life qualification. Sterilization was validated per ISO 11137-1, ISO 11137-2, and AAMI TIR29. Dose substantiation qualification was performed to encompass the larger size per ISO 11737-2 and

	AAMI TIR33. Additionally, packaging was rationalized by prior data and further transit qualification was performed to support the new carton and shipping configurations related to the larger size offering.
Substantial Equivalence to Predicate Devices	Based on the information presented in this submission, the proposed changes do not raise new questions of safety and effectiveness. Therefore, it can be concluded that the SYNTHECEL® Dura Repair is substantially equivalent to the predicate device.