November 12, 2025

Synthes GmbH
Thomas Shea
Manager, Regulatory Affairs
Luzernstrasse 21
Zuchwil, SO 4528
Switzerland

Re: K243715
Trade/Device Name: Synthes Patient Specific Implants
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN
Dated: October 13, 2025
Received: October 14, 2025

Dear Thomas Shea:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jaime Raben -S

Jaime Raben, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243715

Device Name

Patient Specific Implants

Indications for Use *(Describe)*

Patient Specific Implants are intended for the replacement of bony voids in the cranial and craniofacial skeleton (orbital rim, zygoma, and adjacent bone).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Sponsor	**Synthes GmbH**	**Address**
Primary Contact	Thomas Shea Manager, Regulatory Affairs DePuy Synthes	1301 Goshen Parkway West Chester, PA USA T: 610-719-5679 Email: tshea@its.jnj.com
Alternate Contact	Damon Lees Director Regulatory Affairs DePuy Synthes	1301 Goshen Parkway West Chester, PA USA T: 610-308-9140 Email: dlees@its.jnj.com
Date Prepared	October 8, 2025	
Device Trade Name	Patient Specific Implants	
Common Name	Patient Specific Implant	
Classification	Class II	
Regulation	882.5330 Preformed nonalterable cranioplasty plate.	
Product Code	GXN: Plate, Cranioplasty, Preformed, Non-Alterable	
Predicate Device(s)	K220357 MedCAD® AccuShape® Titanium Patient-Specific Cranial Implant	
Reference Device(s)	K033868 / K053199 Synthes Patient Specific Implants	
Device Description Summary	The Patient Specific Implants (PSI) are preformed implantable devices used to reconstruct portions of a patient's skull. The implant is designed using CT data to produce a preformed/pre-shaped implant that will fit the anatomy of a specific patient and is manufactured from PEEK (polyetheretherketone). The PSIs are provided non-sterile and are surgically attached to the native bone using commercially available Synthes 1.3 mm – 2.0 mm screws. The manufacturing process is subtractive manufacturing (CNC milled) from models created and developed from patient specific CT Scan Data. The software used in this process is similar to the software used in the predicate device (K220357). This submission covers the use of software as an enabling technology that can be used as an option for the design of Patient Specific Implants. The device is designed to meet the needs of a specific patient upon request from a physician, and the basic design specifications must fall within the parameters defined in previous clearance for the system under K033868 / K053199. All designs	

	must be approved by the physician prior to manufacture.
Indications for Use	Patient Specific Implants are intended for the replacement of bony voids in the cranial and craniofacial skeleton (orbital rim, zygoma and adjacent bone).
Intended Use Comparison to Predicate	The Patient Specific Implants have the same intended use as predicate device (MedCAD® AccuShape® Titanium Patient-Specific Cranial Implant K220357).
Technological Comparison	The Patient Specific Implants have similar technological characteristics compared to the predicate device, each consisting of a Patient-Specific Cranial Implant manufactured from biocompatible materials attached to the native bone with commercially available plates and screws. Both the subject and predicate devices make use of software to design implants based on a patient's CT data and are available as either single or multi-piece implants provided non-sterile. The difference between the devices is that the subject device is manufactured from PEEK while the predicate is manufactured from Titanium and the subject PEEK implants can be tapered or modified by the surgeon prior to implantation.
Non-clinical Performance Testing	Since there was no change to the design specifications from the previous clearance for the Patient Specific Implants (K033868 / K053199), verification and validation testing focused on the implementation of the design software. The performance of the software has been evaluated by confirming that the outputs meet the input requirements and conform to the user needs and intended use.
Clinical Performance Data	Clinical data was not necessary for the determination of substantial equivalence.
Conclusion	The minor differences in the technological characteristics compared to the predicate do not raise issues related to safety or effectiveness. The results of non-clinical performance data in terms of software verification and validation demonstrate that the subject device is as safe and effective as the predicate device and is therefore substantially equivalent to the predicate.