April 10, 2026

University of Utah, Department of Orthopaedics
% Dave Mcgurl
Vice President, Orthopedic Regulatory Affairs
MCRA, LLC
803 7th Street NW, 3rd Floor
Washington, District of Columbia 20001

Re: K252699
Trade/Device Name: CoAptix S System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: March 10, 2026
Received: March 10, 2026

Dear Dave Mcgurl:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic 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)*
K252699

Device Name
CoAptix S System

Indications for Use *(Describe)*
The CoAptix S System is intended for the fixation of bone fractures, fusions, osteotomies, reconstructions, non-unions, and malunions in adults. The System is indicated for long bones and long bone fragments, pelvic bones (including the sacrum), and the foot.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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THE UNIVERSITY OF UTAH®

510(k) Summary

Device Trade Name: CoAptix S System

Sponsor: University of Utah, Department of Orthopaedics
590 Wakara Way
Salt Lake City, UT 84108

Contact: T. Wade Fallin, M.S.
Research Professor
Phone: (801) 587-2938
Fax: (801) 587-5411

Prepared by: MCRA, LLC

Date Prepared: April 3, 2026

Common Name: Smooth or threaded metallic bone fixation fastener;
Single/multiple component metallic bone fixation appliances and accessories

Classification: 21 CFR 888.3040 (primary);
21 CFR 888.3030

Classification Name: Screw, Fixation, Bone;
Washer, Bolt, Nut

Class: II

Product Code: HWC (primary); HTN

Indications for Use:
The CoAptix S System is intended for the fixation of bone fractures, fusions, osteotomies, reconstructions, non-unions, and malunions in adults. The System is indicated for long bones and long bone fragments, pelvic bones (including the sacrum), and the foot.

Device Description:
The CoAptix S System implants are metallic bone screws, available in multiple lengths, and are intended to be used per the indications for use. The screws are cannulated for use with guidewires for precise placement in bone, the screws are available in headed and headless versions, and an optional washer is available for use with the screws that are headed.

Predicate Devices:
Primary Predicate
DePuy Synthes Cortex and Cannulated Screws (K161616)

Additional Predicate
MedShape DynaFuse Fixation System (K203595)

Materials:
The CoAptix S implants are made from Ti-6Al-4V per ASTM F136 and Nitinol per ASTM F2063.

Performance Data:
The CoAptix S System performance was characterized through the following:

- Torsional Strength Testing per ASTM F543
- Driving Torque Testing per ASTM F543
- Axial Pull-out Strength Testing per ASTM F543
- Static and Dynamic Bending Testing per ASTM F1264 Annex A4
- Pitting Corrosion per ASTM F2129
- Galvanic Corrosion per ASTM G102 as referenced in ASTM F3044
- Fretting Corrosion
- Af Testing per ASTM F2082

No clinical or animal testing was conducted.

Substantial Equivalence & Conclusions:
The CoAptix S System has the same intended use and uses the similar design, materials, principles of operations, and range of sizes as the predicate devices, the DePuy Synthes Cortex and Cannulated Screws (K161616), and MedShape DynaFuse Fixation System (K203595). Side-by-side performance testing demonstrates that the CoAptix S System has equivalent or statistically significantly better performance than its predicates. The CoAptix S System's similarities in technological characteristics to its predicates further support its substantial equivalence. Thus, the CoAptix S System is substantially equivalent to the DePuy Synthes Cortex and Cannulated Screws (K161616) and MedShape DynaFuse Fixation System (K203595).