February 19, 2025

Smith & Nephew
Mandy Coe
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K241666
Trade/Device Name: EVOS Pelvic and Acetabular System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC, HTN
Dated: January 22, 2025
Received: January 22, 2025

Dear Mandy Coe:

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K241666

Device Name

EVOS Pelvic and Acetabular System

Indications for Use *(Describe)*

The EVOS Pelvic and Acetabular System is indicated for fixation of fractures and/or disruptions of the pelvis and acetabulum in skeletally mature patients.

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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510(k) #: K241666

# 510(k) Summary

Prepared on: 2025-01-21

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Smith & Nephew |
| Applicant Address | 1450 Brooks Road Memphis TN 38116 United States |
| Applicant Contact Telephone | 901-949-3344 |
| Applicant Contact | Mrs. Mandy Coe |
| Applicant Contact Email | mandy.coe@smith-nephew.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | EVOS Pelvic and Acetabular System |
| Common Name | Single/multiple component metallic bone fixation appliances and accessories |
| Classification Name | Plate, Fixation, Bone |
| Regulation Number | 888.3030 |
| Product Code(s) | HRS, HWC, HTN |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K162078 | EVOS Small-Fragment Plating System | HRS |
| K140814 | EVOS Mini-Fragment Plating System | HRS |
| K060736 | Smith & Nephew 6.5mm and 8.0mm Cannulated Screws | HWC |
| K170887 | EVOS Small Fragment Plating System | HRS |
| K173293 | EVOS Small Fragment Upper Extremity Plates | HRS |
| K122538 | Acumed Pelvic Bone Plate System | HRS |
| K063166 | ITS Pelvic Reconstruction System | HRS |
| K210935 | ITS Pelvic Reconstruction System (PRS RX & Phoenix) | HRS |
| K221809 | DePuy Synthes 3.5mm Intrapelvic Acetabular System | HRS |
| K993106 | Smith & Nephew Bone Plate System | HRS |

## Device Description Summary

21 CFR 807.92(a)(4)

The subject EVOS Pelvic and Acetabular System consists of Class II bone plate and screw implants. The subject bone plates are available in a variety of shapes and sizes. The subject screws consist of locking and non-locking screws as well as cannulated screws. The subject plates are also compatible with the previously cleared EVOS locking and non-locking screws, and partially and fully threaded osteopenia screws (K140814 S.E. 5/7/2014 and K162078 S.E. 7/27/2016). The proposed plates and screws are manufactured from implant-grade 316L Stainless Steel material and will be available in a sterile packaged condition.

## Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The EVOS Pelvic and Acetabular System is indicated for fixation of fractures and/or disruptions of the pelvis and acetabulum in skeletally mature patients.

## Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the subject devices are substantially equivalent to the indications for the cleared predicates.

## Technological Comparison 21 CFR 807.92(a)(6)

Device comparisons described in this premarket notification demonstrated that the proposed bone plates and screws are substantially equivalent to legally marketed predicates with respect to intended use, indications, and performance characteristics. Both the subject and predicate devices have same operating principle, material, and technological characteristics.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following nonclinical tests were used to determine substantial equivalence:
- Finite element analysis (FEA) was conducted on the subject plates to determine worst case plate for mechanical testing.
- Four Point Bend Fatigue testing of the subject plates per ASTM F382.
- Static Evaluation of the screws per ASTM F543.
- Bending Fatigue testing of the screws per ASTM F1264.
- Magnetic resonance imaging (MRI) compatibility evaluation was done per ASTM F2052, ASTM F2213, ASTM F2182, and ASTM F2119.
- Packaging verification testing was conducted on the subject devices per ASTM F2096 and ASTM F88.

No clinical testing was performed on the subject devices.

The testing detailed in this premarket notification confirms that the subject EVOS Pelvic and Acetabular Plating system is substantially equivalent in performance to the predicate EVOS Plating Systems (K162078, S.E. 11/18/2016 and K140814, S.E. 5/7/2014).