Biomet, Inc
Akash Savalia
Regulatory Affairs Sr. Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581

May 22, 2024

Re: K241014
Trade/Device Name: Biomet Kirschner Wires (K-Wires)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: April 12, 2024
Received: April 12, 2024

Dear Akash Savalia:

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.

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2024.05.22 09:38:14 -04'00'
for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*

K241014

Device Name

Biomet Kirschner Wires (K-Wires)

Indications for Use *(Describe)*

Kirschner Wires are used for;
- As guide pins for insertion of other implants
- Bone reconstructions
- Fixation of bone fractures and osteotomies
- Implanted through the skin for traction applied to the skeletal system

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) #: K241014

510(k) Summary

Prepared on: 2024-04-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Biomet, Inc
Applicant Address	56 East Bell Drive P.O. Box 587 Warsaw IN 46581 United States
Applicant Contact Telephone	(978)908-0222
Applicant Contact	Mr. Akash Savalia
Applicant Contact Email	akash.savalia@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Biomet Kirschner Wires (K-Wires)
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Pin, Fixation, Smooth
Regulation Number	888.3040
Product Code(s)	HTY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K143618	Kirschner Wires, Steinmann Pins	HTY

Device Description Summary

21 CFR 807.92(a)(4)

Biomet Inc manufactures a variety of internal fixation devices intended to aid in the alignment and stabilization of fractures to the skeletal system until healing has occurred. Biomet Kirschner Wires (K-wires) are rigid yet malleable wires with penetrating tips such that they may be inserted through tissue and into bone to allow for traction or fixation of bone fragments as desired or for alignment guides for other bone fixation implants. These wires are available in multiple diameters, same length and unthreaded (smooth) versions.

Biomet Kirschner Wires are single use and provided in both sterile and non-sterile configurations. Unless supplied sterile, metallic internal fixation devices must be sterilized prior to surgical use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Kirschner Wires are used for;
- As guide pins for insertion of other implants
- Bone reconstructions
- Fixation of bone fractures and osteotomies
- Implanted through the skin for traction applied to the skeletal system

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications are similar between the predicate and the subject device.

Technological Comparison

21 CFR 807.92(a)(6)

Comparison of Technological Characteristics:
The Biomet Kirschner wires are similar in intended use and similar in basic shape, dimensions, material, and performance characteristics to the predicate device. There is no change in the fundamental scientific technology shared by both the subject device and predicate device and therefore the technological characteristics do not raise any new questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

o Biomet Kirschner Wires conform to mechanical property specifications of ASTM F138-19 and dimensional property specifications of ASTM F366-17. This data demonstrates the subject devices are substantially equivalent to predicate devices.