September 29, 2023

Auxano Medical LLC
James Price
Senior Design Engineer
8006 Katherine Blvd.
Brecksville, Ohio 44141

Re: K231649
Trade/Device Name: Intraosseous Fusion Device System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 21, 2023
Received: August 21, 2023

Dear Mr. Price:

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,

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)*
K231649

Device Name
Intraosseous Fusion Device System

Indications for Use *(Describe)*
The Intraosseous Fusion Device System is indicated for use in skeletally mature individuals for fracture repair and arthrodesis, osteotomy, joint fusion and fragment fixation appropriate with the size of the implant including:

Minimally invasive reconstruction of fractures and joints; Fractures of the foot and ankle; Osteochrondritis dissecans, Ostero-Chondral Fractures, Other small fragment, cancellous bone fractures, Small joint fusion. Metatarsal and phalangeal osteotomies; Fractures of the tarsals, metatarsals and other fractures of the foot; Avulsion fractures and fractures of metatarsal V; Tarso-metatarsal and metatarso-phalangeal arthrodesis; Tarsal Fusions; Calcaneal and talar fractures, Subtalar arthrodesis. Ankle arthrodesis. Fractures of small joints, such as: Ankle fractures, Navicular fractures, Fractures of the fibula, malleolus, and calcaneus.

The Intraosseous Fusion Device System is not intended for spinal use.

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

Intraosseous Fusion Device System

SUBMITTER
Auxano Medical LLC
8006 Katherine Boulevard
Brecksville, OH 44141
Phone: 440-262-2000

Contact Person: James Price – Senior Design Engineer
Email: James.Price@auxanomedical.net
Date Prepared: August 28, 2023

DEVICE INFORMATION
Trade/Device Name: Intraosseous Fusion Device System
Common Name: Intraosseous Fusion Device System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC

PREDICATE INFORMATION
Predicate Device: K191995 (S4 Screw System; Subchondral Solutions, Inc.)

Additional Predicate Device: K163489 (OrthoSolutions 'System26' Bone Screws; Ortho Solutions UK Limited)

INDICATIONS FOR USE:
The Intraosseous Fusion Device System is indicated for use in skeletally mature individuals for fracture repair and arthrodesis, osteotomy, joint fusion and fragment fixation appropriate with the size of the implant including:
Minimally invasive reconstruction of fractures and joints; Fractures of the foot and ankle; Osteochrondritis dissecans, Ostero-Chondral Fractures, Other small fragment, cancellous bone fractures, Small joint fusion. Metatarsal and phalangeal osteotomies; Fractures of the tarsals, metatarsals and other fractures of the foot; Avulsion fractures and fractures of metatarsal V; Tarso-metatarsal and metatarso-phalangeal arthrodesis; Tarsal Fusions; Calcaneal and talar fractures, Subtalar arthrodesis. Ankle arthrodesis. Fractures of small joints, such as: Ankle fractures, Navicular fractures, Fractures of the fibula, malleolus, and calcaneus.
The Intraosseous Fusion Device System is not intended for spinal use.

DEVICE DESCRIPTION
The Intraosseous Fusion Device (IFD) is a threaded titanium implant that is designed to provide stabilization of bones, bone segments or bone fragments to facilitate arthrodesis. The implant has an interrupted external thread to facilitate placement and fixation. The implant is hollow, which allows packing of bone graft material, and fenestrated, which allows bone growth and formation throughout the implant. The implants come in a variety of diameters (6, 9, 12mm) and lengths (10, 15 & 20mm) to address different anatomy locations. The implants are made from Ti6-6Al-4V alloy. The Intraosseous Fusion Device System includes implants, the instruments necessary to implant them, and the tray system for transport, storage and sterilization. The system is provided non-sterile and

requires steam sterilization at point of use. Single-use metallic implants are time stable. Reusable instruments are inspected in reprocessing for conditions compromising function. All instruments (except for k-wires) are reusable and can be reprocessed.

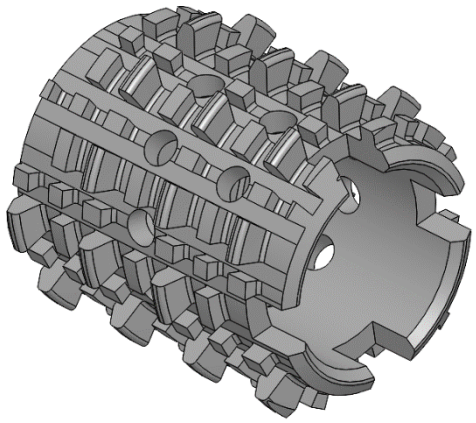

Figure 1. Intraosseous Fusion Device

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATES:

Table 1.

	Subject Device: **Auxano Medical- Intraosseous Fusion Device System**	**Predicate (K191995):** **Subchondral Solutions- S4 Screw**	**Additional Predicate (K163489):** **OrthoSolutions- System26 Bone Screws**
Device Class and Product Code:	Class II; HWC	Class II; HWC	Class II; HWC & HTN
	Substantial Equivalence:	Same	Similar
Sterilization:	Implants & Instruments- provided NON-STERILE; Steam sterilize on-site to SAL of 10^{-6}	Implant & Instruments- provided STERILE	Implants & Instruments- provided NON-STERILE
	Substantial Equivalence:	Different	Similar
Prescription:	Prescription Only	Prescription Only	Prescription Only
	Substantial Equivalence:	Same	Same
Indications for Use:	The Intraosseous Fusion Device System is indicated for use in skeletally mature individuals for fracture repair and arthrodesis, osteotomy, joint fusion and fragment fixation appropriate with the size of the implant including: Minimally invasive reconstruction of fractures and joints; Fractures of the foot and ankle; Osteochrondritis dissecans, Ostero-Chondral Fractures, Other small fragment, cancellous bone fractures, Small joint fusion. Metatarsal and phalangeal osteotomies; Fractures of the tarsals, metatarsals and other fractures of the foot; Avulsion fractures and fractures of metatarsal V; Tarso-metatarsal and metatarso-phalangeal arthrodesis; Tarsal	Minimally invasive reconstruction of fractures and joints; Adjuvant for osteosynthesis in complex joint fractures; Multifragment joint fractures; Simple metaphyseal fractures, Fractures of the wrist, ankle, elbow, and shoulder, Condylar fractures; Osteochrondritis dissecans, Osteochondral Fractures, Ligament avulsion injuries, Ligament fixation, Other small fragment, cancellous bone fractures, Small joint fusion. Areas where accurate screw placement is vital. Metatarsal and phalangeal osteotomies; Fractures of the tarsals, metatarsals and other fractures of the foot; Avulsion fractures and fractures of metatarsal V; Tarso-metatarsal and metatarsophalangeal arthrodesis; Tarsal Fusions; Calcaneal and talar fractures, Subtalar arthrodesis, Ankle arthrodesis. Fractures of small joints, such as: Ankle fractures, Navicular fractures, Fractures of the fibula, malleolus, and calcaneus, Distal tibia and pilon fractures, Acetabular fractures. Other fractures of the pelvic ring; Fractures of the femoral head and	The OrthoSolutions 'System26' cannulated screws (headed and headless compression) and washers are indicated for use over a guide pin or wire for aligned bone fracture repair and arthrodesis, osteotomy, joint fusion and bone fragment fixation appropriate with the size of the screw. Washers of matching size to the headed cannulated bone screw may be used in certain applications for deficient osteopenic bone. The non-cannulated 2.0 (headed, headless compression and Twist-Off) bone screws are applicable, as well, for bone fracture repair and arthrodesis, osteotomy, joint fusion and bone fragment fixation appropriate with the size of the screw. 'System26' non-cannulated 2.0mm (headed, headless compression and Twist-Off) bone screws and cannulated (headed and headless compression) bone screw sizes of 2.0mm, 2.5mm 3.0mm are indicated for treating small bone fractures as well as performing osteotomies, arthrodesis and joining cancellous bone fragments in the upper and lower limb and extremities.

	Subject Device: **Auxano Medical- Intraosseous Fusion Device System**	**Predicate (K191995):** **Subchondral Solutions- S4 Screw**	**Additional Predicate (K163489):** **OrthoSolutions- System26 Bone Screws**
	Fusions; Calcaneal and talar fractures, Subtalar arthrodesis. Ankle arthrodesis. Fractures of small joints, such as: Ankle fractures, Navicular fractures, Fractures of the fibula, malleolus, and calcaneus. The Intraosseous Fusion Device System is not intended for spinal use.	neck, Supracondylar femoral fractures, Slipped capital femoral epiphyses, An adjunct to DHIS in basilar neck fractures, Intercondylar femur fractures, Intracapsular fractures of the hip, Fractures of the distal femur and proximal tibia, Patellar fractures, Tibial plateau fractures. Small fragments of the hand and wrist, Fractures of the carpals and metacarpals, Carnal and metacarpal arthrodesis, Scaphoid fracture and other fractures of the hand, Phalangeal and interphalangeal fractures, Fractures of the ulna and radius. Radial head fractures, Fractures of the olecranon and distal humerus, Humeral head fractures, Ligament fixation at the proximal humerus, Glenoid fractures.	'System26' cannulated bone screw sizes (headless compression and headed with optional matching washer) of 4.0mm, 5.0mm, 6.5mm, and 8.0mm are indicated to be used with large and long bones. Specific indications, which are dependent in part on the diameter of the screw include: Minimally invasive bone fracture/joint reconstructions; Additive osteosynthesis for complex joint fractures; Multiple-fragment joint fractures; Femoral neck and femoral head fractures; Femoral supracondylar fractures; Tibial plateau fractures; Fractures of the head of the humerus; Fractures of the tibia; Cooper fractures of the tibia; Bone fractures of the radius, wrist, ankle, elbow, and shoulder; Ligament fixation of the proximal humerus; Bone fractures of the acetabulum and dorsal pelvic ring; Condylar fractures; Ligament avulsion injuries; Malleolar and navicular fractures; Bone fractures of the calcaneus and talus; Arthrodesis of the ankle joint; Arthrodesis of foot joints and; Avulsion fractures. The OrthoSolutions 'System26' Bone Screws are not intended for spinal use.
	Substantial Equivalence:	Similar	Similar
Intended Use:	Bone fixation of fractures, fusions (arthrodesis), osteotomies and fragments.	Bone fixation of fractures, fusions (arthrodesis) and osteotomies.	Bone fixation of fractures, fusions (arthrodesis), osteotomies and fragments.
	Substantial Equivalence:	Similar	Same
Components:	K-wires, sizers, drills, taps, drivers, driver handles	K-wires, countersink, depth gauge, reamer, driver	K-wires, drill guides, drills, countersinks, depth gauges, drivers, driver handles, forceps, clamps, easy-outs
	Substantial Equivalence:	Similar	Similar

	Subject Device: **Auxano Medical- Intraosseous Fusion Device System**	**Predicate (K191995):** **Subchondral Solutions- S4 Screw**	**Additional Predicate (K163489):** **OrthoSolutions- System26 Bone Screws**
Technical Characteristics:	Threaded Cannulated Headless Fenestrated Interrupted thread	Threaded Cannulated Headless Fenestrated Interrupted thread HA-coated	Threaded Cannulated and Non-cannulated Headed and Headless (Smooth/Threaded)
	Substantial Equivalence:	Similar	Similar
Materials:	Ti-6Al-4V (ASTM F136 & F3001)	Ti-6Al-4V (ASTM F136) (w/HA coating)	Ti-6Al-4V (ASTM F136)
	Substantial Equivalence:	Similar	Same

PERFORMANCE DATA:

- Mechanical testing (torsional strength, driving torque, axial pullout strength) was carried out per ASTM F543 on the subject device and additional predicate, OrthoSolutions System26 bone screws.
- Mechanical testing was carried out per ASTM F2077 on subject device for static and cyclic radial compression.
- Implant cleanliness validation was carried out at implant vendor (Marle Tangible) and internally following subsequent shipping, inspection and warehouse tasks.
- GLP cytotoxicity testing was conducted on the IFD implants and instruments.
- Steam sterilization validation testing was conducted on the IFD system according to ISO 17665-1 and ISO 14937.
- Manual cleaning validation testing was conducted on the worst-case instrument following simulated use cycles according to AAMI TIR12 and AAMI TIR30.
- Shipping simulation was conducted on the IFD system and packaging according to ISTA 3A.

CONCLUSION

The subject Intraosseous Fusion Device System has same intended use and similar indications for use, the similar technology, comparable principles of operation, and similar materials as the identified predicate systems: Subchondral Solutions- S4 Screw (K191995) and OrthoSolutions-System26 Bone Screws (K163489). The IFD System does not raise any new questions of safety or effectiveness as compared to the predicate systems. Performance testing according to ASTM F543 demonstrates substantially equivalent mechanical performance of the subject device as compared to the System26 Bone screws currently on the market. Therefore, the Intraosseous Fusion Device System is substantially equivalent to the identified predicate systems.