Diamond Orthopedic, LLC
% Lauren Smith
Project Engineer
JALEX Medical
30311 Clemens Road, Suite 5D
Westlake, Ohio 44145

May 9, 2018

Re: K180932
Trade/Device Name: Diamond Orthopedic Bone Fixation Screws and Pins
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, JDW, HTY
Dated: April 9, 2018
Received: April 10, 2018

Dear Lauren Smith:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180932

Device Name
Diamond Orthopedic Bone Fixation Screws and Pins

Indications for Use *(Describe)*
Diamond Orthopedic Bone Fixation Screws and Pins are intended to be used as fixation implants for bone fractures, joint fusion, bone reconstruction, or as guide pins for insertion of other implantable devices.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitted by:	Diamond Orthopedic, LLC 1600 Camden Road Charlotte, North Carolina 28203
Date:	04/09/2018
Contact Person:	Lauren Smith
Contact Telephone:	440.541.0060
Contact Fax:	440.933.7839
Device Trade Name:	Diamond Orthopedic Bone Fixation Screws and Pins
Device Classification Name:	Screw, Fixation, Bone Pin, Fixation Smooth or Threaded
Device Classification:	21 CFR 888.3040
Reviewing Panel:	Orthopedic Panel
Product Code:	HWC, JDW, HTY
Primary Predicate Device:	Medical Facet Bone Fixation Screws and Pins (K112727)

Device Description:

Diamond Orthopedic Bone Screws (cortical screws, cancellous screws, and headless compression screws) are available in thread diameters ranging from 1.5mm to 7.3mm, lengths ranging from 6mm to 180mm, and either solid or cannulated, and made of stainless steel or titanium.

Diamond Orthopedic External Fixation Screws are available in thread diameters ranging from 4mm to 6mm, lengths ranging from 60mm to 250mm, and thread lengths ranging from 18mm to 80mm, and made of stainless steel or titanium.

Diamond Orthopedic Kirschner Wires are available in wire diameters ranging from 1.0mm to 2.5mm, in lengths ranging from 100mm to 150mm, 0.7mm to 1.6mm, in lengths ranging from 101.6mm to 304.8mm and are partially or completely threaded, or smooth. Made of stainless steel or titanium.

Diamond Orthopedic Guide Wires are available in wire diameters ranging from 0.8mm to 2.8mm, in lengths ranging from 100mm to 450mm, are partially threaded or smooth. Made of stainless steel, titanium, or cobalt.

Diamond Orthopedic Steinmann Pins are available in wire diameters ranging from 2mm to 4.7mm, in lengths ranging from 228.6mm to 304.8mm, are completely threaded, or smooth. Made of stainless steel or titanium.

510(k) Summary

Intended Use:

Diamond Orthopedic Bone Fixation Screws and Pins are intended to be used as fixation implants for bone fractures, joint fusion, bone reconstruction, or as guide pins for insertion of other implantable devices.

Non-Clinical Testing

The Bone Fixation Screws and Pins are identical in geometry and manufacturing to the predicate device. No new mechanical performance testing was performed. Sterilization validation, shelf life testing, LAL testing (bacterial endotoxin levels), and packaging testing were performed on the subject device.

Substantial Equivalence:

The modified Bone Fixation Screws and Pins have the same intended use, indications for use, principles of operation, and technological characteristics of the predicate. Modifications do not raise new questions of safety or effectiveness. Therefore the modified Bone Fixation Screws and Pins are substantially equivalent to the predicate.