February 20, 2020

Biomet Inc.
Dominique Dompor
Regulatory Affairs Specialist
56 East Bell Drive, PO Box 587
WARSAW IN 46581

Re: K193533
Trade/Device Name: WIN Flexible Nail System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDS
Dated: December 19, 2019
Received: December 20, 2019

Dear Dominique Dompor:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

for

Michael Owens
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193533

Device Name
WIN Flexible Nail System

Indications for Use *(Describe)*
WIN Flexible Nail System
WIN Nails (for use in pediatric patients) are to be used for treatment of long-bone fractures including non-comminuted and comminuted mid-shaft fractures, subtrochanteric fractures, distal third fractures, combination fractures of the shaft and neck, intertrochanteric fractures, combination intertrochanteric and subtrochanteric fractures.

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) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the WIN Flexible Nail System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on September 13, 2019.

Sponsor:
Biomet Inc.
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Warsaw, IN 46581
Establishment Registration Number: 1825034

Primary Contact Person:
Dominique Dompor
Regulatory Affairs Specialist
Telephone: (877) 652-0830 ext. 169

Secondary Contact Person:
Stacy Hutchens
Scientific Affairs Manager
Telephone: (574) 371-9671

Date:
December 19, 2019

Subject Device:

Trade Name: WIN Flexible Nail System
Common Name: Nail, Fixation, Bone

Classification Name:
Single/multiple component metallic bone fixation appliances and accessories.

- JDS – Nail, Fixation, Bone (21 CFR §888.3030)

Predicate Device(s):

Primary Predicate	**510(k) Number**
Pediatric Fixation Rods	K000764
Alternate Predicate	**510(k) Number**
2mm Pediatric Flex Nail	K022531

Purpose and Device Description:

The subject WIN Flexible Nail System is made of titanium alloy, which has been continuously made commercially available since the 1950s. This device is to

	be implanted by insertion into long bones for fixation of fractures.
	The purpose of this submission is:
	• To further identify and clarify cumulative changes made to the system since original clearance:
	  o An extension to the WIN Flexible Nail product line offering;
	  o Added surface treatment to aid in visual differentiation of nail sizes;
	  o A change to the manufacturing location;
	  o A change to the sterilization vendor site;
	• To update labeling in order to bring the Instructions for Use up to current practices.

Intended Use and Indications for Use:	This device is intended for osteosynthesis. The WIN Flexible Nail System is to be used for treatment of long-bone fractures including non-comminuted and comminuted mid-shaft fractures, subtrochanteric fractures, distal third fractures, combination fractures of the shaft and neck, intertrochanteric fractures, combination intertrochanteric and subtrochanteric fractures.
Summary of Technological Characteristics:	The rationale for substantial equivalence is based on consideration of the following characteristics: • **Intended Use:** Identical to predicate • **Indications for Use:** Identical to predicate • **Materials:** Identical to predicate • **Design Features:** Similar to predicate • **Sterilization:** Identical to predicate
Summary of Performance Data: (Nonclinical and/or Clinical)	**Non-Clinical Tests:** • None provided **Clinical Tests:**

	• None provided
Substantial Equivalence Conclusion:	The subject WIN Flexible Nail System has identical intended use and indications for use as the predicate devices. The subject device has similar technological characteristics to the predicates, and the information provided herein demonstrates that: • any differences do not raise new questions of safety and effectiveness; and • the subject devices are at least as safe and effective as the legally marketed predicate devices.