DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 16, 2017

Biopro, Inc.
% Al Lippincott
Biomedical Engineer & Consultant To Biopro, Inc.
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, Minnesota 55372

Re: K162674
Trade/Device Name: BioPro Foot Plating Systems
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
Dated: May 3, 2017
Received: May 12, 2017

Dear Al Lippincott:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) NUMBER: **K162674**

DEVICE NAME: **BioPro Foot Plating Systems**

The ***intended use*** of the *BioPro Foot Plating Systems* is to draw two or more aligned bone fragments together to facilitate healing in an adult patient and is composed of the following *bone plate categories*:

I. Forefoot System:

The BioPro *Forefoot Plating System* is **Indicated for Use** in fixation of small bones and small bone fragments in the foot (Phalanges and Metatarsals) for stabilization of fractures, joint fusions, osteotomies , nonunions, malunions, reconstruction of small bones, revision surgeries and replantations in an adult patient.
The Forefoot System is not for Spinal Use.

II. Mid & Hindfoot System:

The BioPro *Mid & Hindfoot Plating System* is **Indicated for Use** in fixation of medium/large bones and medium/large bone multi-fragments in the foot (Cuneiform, Cuboid, Navicular, Talus and Calcaneus) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of medium/large bones, revision surgeries and replantations in an adult patient.
The Mid & Hindfoot System is not for Spinal Use.

III. Ankle Fracture System:

The BioPro *Ankle Fracture System* is **Indicated for Use** in:
1). Fixation of fractures of the distal tibia included, but not limited to, ankle fractures, perarticular fractures, corrective osteotomies, non-unions, intra- and extra- articular and distal tibia fractures with a shaft extension, and malleolar fractures;
2). In intra- and extra articular fractures, osteotomies, medial malleolar fractures and non-unions of the metaphyseal and diaphyseal region of the distal fibula;
3). In distal tibia/fibula long bones which include the metaphyseal and diaphyseal regions of the tibia and fibula in the ankle.
The Ankle Fracture System is not for Spinal Use.

Prescription Use **XXXXXXXX** AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

In Accordance with 21 CFR 807.92 of the Federal Code of Regulations

NAME OF FIRM: BioPro, Inc.
2929 Lapeer Road
Port Huron, MI 48060
www.bioproimplants.com

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372
Tel. No. 952-492-5858
e-mail: **allippincott@msn.com**

DATE: May 3, 2017

TRADE NAME: **BioPro Foot Plating Systems**

COMMON NAME: Plate, Fixation, Bone; Screw, Fixation, Bone.

CLASSIFICATION: Single/multiple component metallic bone fixation applieances and accessories, **Class II** (*21CFR, Sec. 888.3030*)

Smooth or threaded metallic bone fixation faxtener, **Class II** (*21CFR, Sec. 888.3040*)

DEVICE PRODUCT CODE: **HRS**

SUBSEQUENT PRODUCT CODE: **HWC**

SUBSTANTIALLY EQUIVALENT DEVICES:

	Forefoot System	Mid & Hindfoot System	Ankle Fracture System
Primary Predicates	**K072740** Mondeal-Extremity Bone Fixation - M2 System	**K111678** OrthoSolutions – Extremity Fixation Implants for Osteosynthesis - FPS System	**K001945** Synthes – Medial Distal Tibia Plate System
Additional Predicates	**K091479 & K142581** Medartis – APTUS Foot System	**K091479 & K142581** Medartis – APTUS Foot System	**K073460 & K083213** Synthes – LCP Distal Fibula Plate System
	K140376 & K141992 Stryker – VariAx 2 Foot Locking Plate System	**K140376 & K141992** Stryker -VariAx 2 Foot Locking Plate System	**K063672** I.T.S. – Fibula Plate Prolock with Angular Stability System
	K090692 Wright – ORTHOLOC 2.0/2.4 Plate System	**K100776** Synthes – LCP Variable Angle Midfoot System	**K092812 & K013248** Synthes – LCP Anterolateral Distal Tibia Plate System
	K100776 Synthes – LCP Variable Angle Forefoot System	**K061808** Dacrco International, Inc. - Darco Locking Bone Plate System	

Additional Predicates Continued:	**Forefoot System**	**Mid & Hindfoot System**	**Ankle Fracture System**
	K141784 OrthoSolutions - ULTOS Plating System	**K121651, K120359, K090692** Wright – ORTHOLOC 3Di Midfoot - Cotten, Evans, MTP, Lapidus, Ankle Fusion Plating Systems	**K013248, K082807** Synthes – LCP Distal Tibia Plate & LCP Compression Plate Systems & Ankle Arthrodesis Plates
	K001945 Synthes. – Medial Distal Tibia Plates	**K123000** Integra – Total Foot System – MOWO & Rearfoot	
	K090675 Smith & Nephew - VLP Foot Plating/Screw System	**K110908** Medartis Ag - Aptus Foot 3.5 System	
	K121651 Wright – ORTHOLOC 3Di Flatfoot System		

Reference Predicates:	
	K922500 BioPro - PSL Total Hip System
	K132510 BioPro – Infinity Plate Anchor System

DEVICE DESCRIPTION: The *BioPro Foot Plating Systems* consists of Predicate Foot and Ankle Bone Plate and Locking Screw implant components found with many companies with orthopedic markets in the United States. These *Foot Bone Plate Systems* fracture fixation & osteotomy implant devices consist of the following categories:

1. **Forefoot System**
2. **Mid & Hindfoot System**
3. **Ankle Fracture System**

A brief and concise description of each system is as follows:

1. The BioPro **Forefoot System** is designed to address a variety of indications in forefoot reconstruction fixation/osteotomy surgery. The system is composed of many locking plate types which include: 1). Straight Fracture Plates, 2). T-Shaped Fracture Plates, 3). Y-Shape Fracture Plates, 4). L-Shaped Fracture Plates, 5). Cloverleaf Fracture Plates, 6). TMT 1 Medial Fusion Plates, 7). Open Wedge Fusion Plates, 8). MTP Fusion Plates, 9). MTP Fusion Revision Plates, and 10). Dorsal TMT 1 Step Fusion Plates, - in various plate lengths, Right & Left versions. The System will incorporate both Cortical Locking Screws and standard Cortical Screws in 2.0mm, 2.5mm, 2.8mm, 3.0mm and 3.5mm sizes in various lengths. All plates are composed of Medical Grade CP Titanium material (to ASTM F67) with an Anodized Type II surface treatment. All screws are composed of Medical Grade 6-4 Alloyed Titanium material (to ASTM F136) color anodized for sizing.

DEVICE DESCRIPTION: A full set of Ancillary Instrumentation (Depth Gauge, Drill Guides, Drill Bits, Screwdrivers, Retractors, Bending Irons, K-wire with stop, Distraction/ Compression Device and MTP Fusion Reamers) is available with the system.
The BioPro *Forefoot System* is offered both EO **STERILE** and **Non-sterile** for **single-use**.

2. The BioPro **Mid & Hindfoot System** is designed to address a variety of indications in midfoot & hindfoot reconstruction fixation/osteotomy surgery. The system is composed of many locking plate types which include:
1). Straight Fracture/Fusion Plates, 2). T-Shaped Fracture/Fusion Plates, 3). L-Shaped Fracture/Fusion Plates, 4). Cloverleaf Fracture/Fusion Plates, 5). X-Shaped Fracture/Fusion Plates, 6). Retangular Fracture/Fusion Plates, 7). Cotton Osteotomy Plates, 8). Dwyer Step Plates, 9). Evans Osteotomy Plates, 10.) Plantar TMT Plates, 11). Distal Medial & 3 - 4 Column Plates and 11). ORIF & Standard Calcaneal Plates – in various plate lengths, Right & Left versions.
The System will incorporate both Cortical Locking Screws and standard Cortical Screws in 3.0mm, 3.5mm and 4.0mm sizes in various lengths. All plates are composed of Medical Grade CP Titanium material (to ASTM F67) with an Anodized Type II surface treatment. All screws are composed of Medical Grade 6-4 Alloyed Titanium material (to ASTM F136) color anodized for sizing.
A full set of Ancillary Instrumentation (Depth Gauge, Drill Guides, Drill Bits, Screwdrivers, Retractors, Reduction Forcepts, Bending Pliers, Osteotomes, K-Wires with stop and Distraction/Compression Device) is available with the system.
The BioPro *Mid & Hindfoot System* is offered both EO **STERILE** and **Non-sterile** for **single-use**.

3. The BioPro **Ankle Fracture System** is designed to address a variety of indications in ankle reconstruction mid-shaft and distal tibia/fibula fixation surgery. The system is composed of many locking plate types which include:
1). Distal Fibula Plates, 2). Medial Distal Tibia Plates, 3). AnteroLateral Distal Tibia Plates, 4). Posterior Distal Tibia T-Plates, 5). Straight Low Contact Plates, and 6). Straight 1/3 Tubular Plates – in various plate shapes, lengths, Right & Left versions. The System will incorporate both Cortical Locking Screws and standard Cortical Screws in 2.8mm, 3.0mm, 3.5mm and 4.0mm sizes in various lengths. All plates are composed of either Medical Grade CP Titanium (to ASTM F67) or 6-4 Alloyed Titanium (to ASTM F136) materials with an Anodized Type II surface treatment. All screws are composed of Medical Grade 6-4 Alloyed Titanium material (to ASTM F136) color anodized for sizing.
A full set of Ancillary Instrumentation (Depth Gauge, Drill Guides, Drill Bits, Screwdrivers, Retractors, Reduction Forcepts, Bending Pliers, Osteotomes, K-Wires with stop, and Distraction/Compression Device) is available with the system.
The BioPro *Ankle Fracture System* is offered both EO **STERILE** and **Non-sterile** for **single-use**.

INTENDED USE: The ***intended use*** of the *BioPro Foot Plating Systems* is to draw two or more aligned bone fragments together to facilitate healing in an adult patient and is composed of the following *bone plate categories*:

I. Forefoot System:

The BioPro *Forefoot Plating System* is **Indicated for Use** in fixation of small bones and small bone fragments in the foot (Phalanges and Metatarsals) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of small bones, revision surgeries and replantations in an adult patient.
The Forefoot Plating System is not for Spinal Use.

II. Mid & Hindfoot System:

The BioPro *Mid & Hindfoot Plating System* is **Indicated for Use** in fixation of medium/large bones and medium/large bone multi-fragments in the foot (Cuneiform, Cuboid, Navicular, Talus and Calcaneus) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of medium/large bones, revision surgeries and replantations in an adult patient.
The Mid & Hindfoot Plating System is not for Spinal Use.

III. Ankle Fracture System:

The BioPro *Ankle Fracture System* is **Indicated for Use** in:
1). Fixation of fractures of the distal tibia included, but not limited to, ankle fractures, perarticular fractures, corrective osteotomies, non-unions, intra- and extra- articular and distal tibia fractures with a shaft extension, and malleolar fractures;
2). In intra- and extra articular fractures, osteotomies, medial malleolar fractures and non-unions of the metaphyseal and diaphyseal region of the distal fibula;
3). In distal tibia/fibula long bones which include the metaphyseal and diaphyseal regions of the tibia and fibula in the ankle.
The Ankle Fracture System is not for Spinal Use.

NON-CLINICAL TESTING: An *Engineering Analysis* was performed to evaluate plate bending strength and bending stiffness. Also, an *Engineering Analysis* was performed to evaluate screw insertion/removal torque, yield torque, and axial pullout strength. A *Biocompatability Risk Assessment* was performed. *Pyrogen bacterial endotoxin levels* were evaluated using the LAL method.

CLINICAL TESTING: Clinical data was not submitted.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS The *BioPro Foot Plating Systems* is **similar** in Material, Design and Indications to Predicate Systems legally marketed in the US.

CONCLUSIONS: Based on the similarity in Material, Geometry, Design, and Indications for Use, as well as all Engineering Analysis, the *BioPro Foot Plating Systems* have been demonstrated to be Substantially Equivalent (SE) to the Predicate Devices.