DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 13, 2017

Biopro, Inc.
% Al Memmolo
President
Convergent Clinical, Inc.
6648 Surf Crest St.
Carlsbad, California 92011

Re: K163627
Trade/Device Name: Shotel Ankle Arthrodesis Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: August 10, 2017
Received: August 11, 2017

Dear Al Memmolo:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)* K163627

Device Name
Shotel Ankle Arthrodesis Nail System

Indications for Use *(Describe)*

The Shotel Ankle Arthrodesis Nail System is intended for the following:

- Charcot Foot
- Avascular necrosis of the talus
- Failed total ankle arthroplasty
- Trauma (malunited tibial pilon fracture)
- Severe deformity or instability as a result of talipes equinoivarus, cerebral vascular accident, paralysis or other neuromuscular disease
- Revision ankle arthrodesis
- Neuroarthropathy
- Rheumatoid arthritis
- Osteoarthritis
- Pseudoarthrosis
- Post-Traumatic arthrosis
- Previously infected arthrosis
- Severe end stage degenerative arthritis
- Severe defects after tumor resection
- Pantalar arthrodesis

Type of Use *(Select one or both, as applicable)*

[X] 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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BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO

General Information

Applicant:	BioPro, Inc. 2929 Lapeer Road Port Huron, MI 48060
Contact Person:	Al Memmolo Convergent Clinical, Inc. Carlsbad, CA 92011
Date Prepared:	August 10, 2017

Device Description

Trade Name:	Shotel Ankle Arthrodesis Nail System
Common Name:	Intramedullary Nail
Product Code:	HSB - Rod, Fixation, Intramedullary And Accessories
Classification:	Class II – 21 CFR § 888.3020 – Intramedullary Fixation Rod
Predicate Devices:	Ascension® Ankle Fusion Nail System - K100925 Howmedica Osteonics Asnis III Cannulated Screw System (K000080) Nexa Orthopedics Nexa Bone Screw System (K053394)

Product Description

The Shotel Ankle Arthrodesis Nail System is an implantable intramedullary system of fusion nails, bone screws, a nail cap and a set of instruments for primary ankle fusion. The curved fusion nail has 6 screw holes that can accommodate up to 6 bone screws and is available in seven (7) diameters in two configurations, left and right. The four (4) distal cross locking holes provide the surgeon with either a static or dynamic cross locking hole in alternative 90 degree orientation configurations. The 5mm fixation bone screws are offered in 27 lengths and the nail caps are available in two configurations; standard nail cap length and a plus 5 mm nail cap length affording the surgeon the ability to slightly adjust the final nail assembly length. All three implant components are manufactured from titanium Ti-6Al-4V and are single use only. Components are offered sterile and non-sterile.

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- Pantalar arthrodesis

TECHNOLOGICAL CHARACTERISTICS

The Shotel Ankle Arthrodesis Nail System has similar physical and technological characteristics to the predicate devices since all implantable devices are manufactured from the same material and have the same principle of operation; fixation of fractures, fusions, or osteotomies, of bones.

PERFORMANCE DATA

All necessary testing has been performed with the Shotel Ankle Arthrodesis Nail System to assure substantial equivalence to the predicate devices. Testing included primary stiffness, fusion-site compression, primary bending stiffness and mechanical and fatigue testing in accordance with ASTM F1264. Pyrogen testing was performed on the subject implants and it was confirmed that the implants meet the 20 EU/device testing limit.

SUBSTANTIAL EQUIVALENCE

Upon reviewing the technical information provided in this submission and comparing intended use, principle of operation, performance data, and overall technological characteristics, the Shotel Ankle Arthrodesis Nail System is determined to be substantially equivalent to existing legally marketed devices.