510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

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

OCT 2 4 2013

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: July 31, 2013

TRADE NAME: **BioPro - Infinity™ Plate Anchor System**

COMMON NAME: Soft-tissue Fixation Plate and Screw

DEVICE NAME:
Fastener, Soft-tissue
Washer, Bolt Nut
Screw, Fixation, Bone

CLASSIFICATION:
Single/multiple Component Metallic Bone Fixation Appliances and Accessories, Class II (21CFR, Sec. 888.3030)

Smooth or Threaded Metallic Bone Fixation Faxtener, Class II (21 CFR, Sec. 888.3040)

DEVICE PRODUCT CODE: **HTN**

SUBSEQUENT PRODUCT CODE: **HWC**

SUBSTANTIALLY EQUIVALENT DEVICE
Synthes – Metallic Spiked Washers (**K013806**)

DEVICE DESCRIPTION: The *BioPro- Infinity™ Plate Anchor System* is a multiple plate system composed of a: 1). 2-hole Curved Plate, 2). 1-hole 10mm Plate, 3). 1-hole 12mm Plate, 4). 1-hole 14mm Plate, 5). 3-hole Flat Straight Plate, and 6). 3-hole T-Plate. Two(2) 3.0mm Cancellous Screws in a 15mm and 20mm length accompany the system for fixing the plate through soft-tissue to bone. Both the plates and screws are manufactured from 6-4 Alloyed Titanium to ASTM F136 with an anodize Type II surface treatment. Ancillary screwdriver and K-wire instrumentation is offered as 'sterile' and disposable and is made available for implantation and removal of the device. The plate and screw implant combination with instrumentation is sold in a '**sterile**' condition for single-use. The sterilization method used is Ethylene Oxide.

INTENDED USE: The *BioPro - Infinity™ Plate Anchor System* is indicated for ligament reattachment or fixation. The BioPro Infinity™ Plate and Screw(s) is supplied 'sterile' and intended for 'single-use' only. The system is not intended for spinal use.

EQUIVALENCE: The *BioPro - Infinity™ Plate Anchor System* is Substantially Equivalent(SE) to the predicate system listed.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS The *BioPro - Infinity™ Plate Anchor System* is Similar in Material, Geometry Design/Markings, and Indications to the Synthes Metallic Spike Washers currently sold in the U.S. market.

SUMMARY OF SAFETY AND EFFECTIVENESS: The *BioPro - Infinity™ Plate Anchor System* is shown to be safe and effective for use as '**sterile**' and for **single-use** in a surgical setting.

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

October 24, 2013

BioPro, Incorporated
% Mr. Al Lippincott
Engineering Consulting Services, Incorporated
3150 East 200th Street
Prior Lake, Minnesota 55372

Re: K132510
Trade/Device Name: BioPro – Infinity™ Plate Anchor System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN, HWC
Dated: October 8, 2013
Received: October 16, 2013

Dear Mr. 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

for Erin D. Keith

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: **K132510**

DEVICE NAME: **BioPro - Infinity™ Plate Anchor System**

The BioPro - Infinity™ Plate Anchor System is indicated for ligament reattachment or fixation. The BioPro Infinity™ Plate and Screw(s) is supplied 'sterile' and intended for 'single-use' only. The system is not intended for spinal use.

Prescription Use **XXXX** 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)

Elizabeth L. Frank -S

Division of Orthopedic Devices