510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

JUN 18 2013

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

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: February 1, 2013

TRADE NAME: **BioPro Kwick-Wire™ Universal Screw System**

COMMON NAME: Pin, Fixation, Threaded;
Washer, Bolt Nut

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

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

DEVICE PRODUCT CODE: **JDW**

SUBSEQUENT PRODUCT CODE: **HTN, HWC**

SUBSTANTIALLY EQUIVALENT DEVICES
DePuy – Rockwood Clavicle Pin (**K991649**)
Onyx Medical – Hagie Pin (**K903258**)
KMI Kinetikos Medical – Kompressor Compression Screw (**K040356**)
Millenium Medical (now OrthoPediatrics) – PWC Pecutaneous Compression Wire (**K031050**)

DEVICE DESCRIPTION: The *BioPro Kwick-Wire™ Universal Screw System* comes in two diameter pin sizes of 2.5mm and 3.0mm and in a length of 4.0in. and is used for reduction and fixation of fractures appropriate for the size of the device. A mating compression nut of either the 2.5mm or 3.0mm size is mated with the proper pin size. Both the pin and nut are manufactured from either high strength 6-4 Alloyed Titanium to ASTM F136 or high strength 316 LVM Stainless Steel to ASTM F138. Ancillary instrumentation is available for device implantation and removal. The implant is sold in a '**sterile**' condition for **single-use**. The sterilization method used is Ethylene Oxide.

BioPro, Inc. Kwick-Wire™ Universal Screw System - 510(k) Summary – K130298:

INTENDED USE:

The *BioPro Kwick-Wire™ Universal Screw System* is indicated for use in the internal fixation of fractures, fusions and revisions. The system is intended for but not limited to hand surgery, orthopedic surgery and podiatric surgery – but is not intended for Spinal Use.

EQUIVALENCE:

The *BioPro Kwick-Wire™ Universal Screw System* is substantially equivalent(SE) to the predicate systems listed. No nonclinical testing was used in the determination of substantial equivalence.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The *BioPro Kwick-Wire™ Universal Screw System* is Similar in Material, Geometry Design/Markings, and Indications to other predicate system(s) currently sold in the U.S. market.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The *BioPro Kwick-Wire™ Universal Screw 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

June 18, 2013

BioPro, Incorporated
% Engineering Consultant Services, Incorporated
Mr. Al Lippincott
BioMedical Engineer & Consultant
3150 East 200th Street
Prior Lake, Minnesota 55372

Re: K130298
Trade/Device Name: BioPro Kwick-Wire™ Universal Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: JDW, HTN, HWC
Dated: March 8, 2013
Received: March 21, 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 Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) NUMBER: **K130298**

DEVICE NAME: **BioPro Kwick-Wire™ Universal Screw System**

The *BioPro Kwick-Wire™ Universal Screw System* is indicated for use in the internal fixation of fractures, fusions and revisions. The system is intended for but not limited to hand surgery, orthopedic surgery and podiatric surgery – but 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