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510K Summary

DEC 15 2008

BioPro Bipolar Head

August 25, 2008

1. Submitter: BioPro, Inc.
17 17th Street
Port Huron, MI 48060

Contact: David Mrak
Director of Product Dev.
(810) 982-7777

2. Device Name

Proprietary Name:	BioPro Bipolar Head
Common Name:	Hip prosthesis, uncemented
Classification Name:	Hip joint femoral metal/polymer cemented or uncemented prosthesis
Regulatory Class:	Class II per 21 CFR §888.3390

3. Intended Use

The BioPro Bipolar Head is intended for use in combination with a BioPro femoral stem for uncemented primary or revision arthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:

- Femoral neck and trochanteric fractures of the proximal femur;
- Osteonecrosis of the femoral head;
- Revision procedures where other devices or treatments for these indications have failed.

4. Device Description

The BioPro Bipolar Head consists of a factory assembled UHMWPE liner in a cobalt chrome outer shell, and UHMWPE retention ring. These bipolar heads include outer diameters ranging from 38 to 60 mm, in 1 mm increments, to properly fit the patient anatomy. The smaller bipolar heads (38 to 42 mm) have an inner diameter that mates with a 22 mm diameter femoral head; the larger bipolar heads (43 mm to 60 mm) have an inner diameter that mates with a 28 mm diameter femoral head. The BioPro Bipolar Head may be used in conjunction with a BioPro femoral stem (K882146) for arthroplasty.

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5. Predicate Device Comparison

Substantial equivalence is claimed to the Pivot Bipolar Femoral Head (K882146) distributed by Ortho Development and the PLUS Bipolar Prosthesis (K982447) distributed by Plus Orthopaedics (now Smith & Nephew). The following table summarizes the similarities and differences between the BioPro Bipolar Head and these predicate devices:

	BioProBipolar Head	**Ortho Development Pivot Bipolar Head**	**Plus Orthopedics PLUS Bipolar Prosthesis**
510(k) Number	Pending	K050966	K982447
FDA Product Code	KWY	KWY	KWY
DESIGN			
Head-Liner-Shell	CoCr-UHMWPE-CoCr	CoCr-UHMWPE-CoCr	CoCr-UHMWPE-CoCr
Head Outer Diameter	38 to 60 mm in 1 mm increments	38 to 60 mm in 1 mm increments	43 to 60 mm in 1 mm increments
Self-aligning (eccentric head)	Yes	Yes	Yes
Liner Inner Diameter	22.225 or 28 mm	22.225 or 28 mm	28 mm
Liner-Head Assembly	Head snap-fit into bipolar liner	Head snap-fit into bipolar liner	Head held in by retention ring
UHMWPE retention ring	Yes	Yes	Yes
MATERIALS			
Outer shell	Cobalt chromium (ASTM F75)	Cobalt chromium (ASTM F75)	Cobalt chromium (ASTM F75)
Liner and retention ring	UHMWPE (ASTM F648), EtO sterilized (not highly crosslinked)	UHMWPE (ASTM F648), gamma sterilized (not highly crosslinked)	UHMWPE (ASTM F648), EtO sterilized (not highly crosslinked)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BioPro, Inc.
% Mr. David Mrak
Director of Product Development
17 Seventeenth St.
Port Huron, Michigan 48060

DEC 15 2008

Re: K082705
Trade/Device Name: BioPro Bipolar Head, Models 18130 - 18152
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWY
Dated: August 15, 2008
Received: September 16, 2008

Dear Mr. Mrak:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082705 (pg 1/1)

Device Name: BioPro Bipolar Head

Indications for Use:

The BioPro Bipolar Head is intended for use in combination with a BioPro PSL Hip System femoral stem for uncemented primary or revision arthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:

- Femoral neck and trochanteric fractures of the proximal femur;
- Osteonecrosis of the femoral head;
- Revision procedures where other devices or treatments for these indications have failed.

Prescription Use__X____ 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)

Neil R. P. Ogden for

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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