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Section XII: 510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990

510(k) Summary

NAME OF FIRM:	BioPro, Inc.. 17 Seventeenth St.. Port Huron, MI 48060
510(k) FIRM CONTACT:	Dave Mrak
TRADE NAME:	BIOPRO TARA Femoral Resurfacing Component
COMMON NAME:	Femoral Resurfacing Component
CLASSIFICATION:	Prosthesis, Hip, Femoral Resurfacing (see 21 CRF, Sec. 888.3400).
DEVICE PRODUCT CODE:	KXA
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy ASR Resurfacing Femoral Heads (**K032659**) Cormet 2000 Hemi Hip Metallic Resurfacing Prosth. (**K994153**) Biomet Press-Fit Head Resurfacing Device (**K023188**) Wright Medical CONSERVE Femoral Surface Replacement
DEVICE DESCRIPTION:	The all-metal cobalt chrome TARA Resurfacing device is a single unit component and is porous coated on the inner cylindrical wall and ceiling only. The cobalt chrome porous coating is a –45 +60 Mesh x .030" thick surface coating. The all-metal TARA is only avaiable in the short stem version, again with nine head sizes from 38mm to 55mm in 2 mm increments. The all-metal TARA is fixed to the bone with cement.
INTENDED USE:	***Indications for use*** include a severe disabling and/or painful hip associated with the following indications: 1) Osteoarthritis, 2) Traumatic arthritis, 3) Rheumatoid arthritis, 4) Advanced avascular necrosis, 5) Congentital hip dysplasia, and 6) Slipped captial femoral epiphysis. Additional indications include other abnormalities where major pathology affects the femoral head; where the acetabular cavity is normal and not deformed or weakened; and where acetabular replacement is either not required or not desirable.
BASIS OF SUBSTANTIAL EQUIVALENCY:	The BIOPRO all-metal TARA Femroal Resurfacing component is substantially equivalent to the DePuy, Corin, Biomet, and Wright Medical Femoral Resurfacing Hip components.
SUMMARY OF SAFETY AND EFFECTIVENESS:	The BIOPRO TARA Femoral Resurfacing all-metal system are shown to be safe and effective for use in Hemi Resurfacing for the femoral head in the hip.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2005

Mr. David Mrak
Director of Product Development
Biopro Incorporated
17 Seventeenth Street
Port Huron, Michigan 48060

Re: K043542
Trade/Device Name: TARA Femoral Resurfacing
Regulation Number: 21 CFR 888.3400
Regulation Name: Hip joint femoral (hemi-hip) metallic resurfacing prosthesis
Regulatory Class: II
Product Code: KXA
Dated: April 4, 2005
Received: April 6, 2005

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 Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO
17 Seventeenth Street,
Port Huron, MI 48060
(810) 982-7777 Fax (810) 982-7794

510(k) NUMBER: K043542

DEVICE NAME: TARA Femoral Resurfacing

INDICATIONS FOR USE:

Indications for use include a severe disabling and/or painful hip associated with the following indications: 1) Osteoarthritis, 2) Traumatic arthritis, 3) Rheumatoid arthritis, 4) Advanced avascular necrosis, 5) Congentital hip dysplasia, and 6) Slipped captial femoral epiphysis. Additional indications include other abnormalities where major pathology affects the femoral head; where the acetabular cavity is normal and not deformed or weakened; and where acetabular replacement is either not required or not desirable.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use

(Per 21 CFR 801.109) (Optional Format)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

Section XI

510(k) Number K043542