Biologically Oriented Prostheses

BIOPRO

Value Analysis Resource Guide
MPJ Hemi Implants

Contents

Company Information

Founded in 1987, BioPro Inc. is an independently owned medical device manufacturer focused on creating solutions that improve patient's lives.

As an FDA registered and ISO certified manufacturer, BioPro designs, develops, manufactures, and distributes products for companies across the globe.

Federal Tax ID: 38-3470922

Address:
2929 Lapeer Rd,
Port Huron, MI 48060

Contacts

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(810) 982-7794

Website:
www.bioproimplants.com

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Product Overview

Description

BioPro Hemi Implants are simple to implant, remove the minimum amount of bone possible, and preserve the anatomy of the toe. The implants are an excellent alternative to arthrodesis, offering patients pain relief and motion.[1-12]

Benefits

- 65+ years of successful clinical use with studies reporting on average 95%+ implant survivorship[1-12]
- 97% satisfaction at 8.3 years[1]
- Immediate weight bearing at the discretion of the surgeon allowing patients to return to activity on average 5 weeks faster than fusion patients.[1]
- Resurfacing only one side of the joint allows for minimal bone removal, while still providing pain relief by preventing bone on bone articulation[9]
- Proven to last 20+ years[9]

Indications for use:

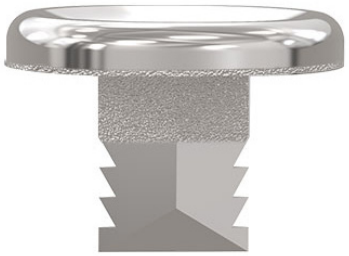
1. A press fit implant for arthritic degradation of the metatarsophalangeal joint that has resulted in disabling pain, limited motion and loss of the normal ambulatory function of the forefoot.
2. Degenerative arthritis
3. Rheumatoid arthritis
4. Bunion deformity associated with arthritis of the metatarsalphalangeal joint

Contraindications:

1. A general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure.
2. An active infection or a previous infection of the lower extremity that has not been quiescent for at least six months.
3. A local or systemic infection.
4. Significant deficiency in the vascular supply to the extremity.
5. Severe structural deficiency of the sub-chondral bone that may result in insufficient support for the prosthesis.
6. A condition of the toe which may lend itself to a more conservative procedure.
7. Severe compromise of the supporting muscles or ligaments about the toe.

Implant Options

STANDARD (NPC)
OVERVIEW Ideal for good quality bone
PROFILE 2.5mm
MATERIAL Cobalt Chrome or Titanium
SIZES 5



POROUS COATED (PC)
OVERVIEW Improved biological fixation
PROFILE 2.5mm + 1mm coating
MATERIAL Cobalt Chrome or Titanium
SIZES 5

HEMIEDGE™
OVERVIEW Reduced chance of overgrowth, migration, or implant subsidence
PROFILE 2.5mm + 1mm edge
MATERIAL Cobalt Chrome
SIZES 5

LESSER
OVERVIEW Designed for digits 2-5
PROFILE 2.0mm
MATERIAL Cobalt Chrome
SIZES 9

Competition

Advantages over other phalangeal based hemi implants

- The BioPro MPJ Hemi system is the most comprehensive phalangeal based Hemi implant system available on the market
- Titanium option available for patients with nickel sensitivity
- Porous and Non-Porous coated option allows surgeon to choose intra-operatively based on patient's bone quality
- Simple, color-coded instrumentation helps ensure consistent, reproducible results
- Low profile, allows for minimal bone removal and successful revision to fusion if necessary
- Sterile packaged implant, reduce sterilization costs

Label and Packaging

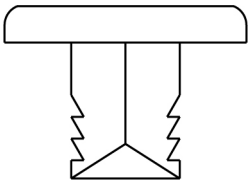
Sterilized with ethylene oxide gas.

Caution

For one procedure only. Do not re-sterilize. Do not use if package is open or damaged. This is a single use device. Re-use of this device can result in the transfer of materials not limited to bone, tissue, blood, or infectious disease. The device is provided sterile and re-sterilization of the device has not been validated.

TOE JOINT

FIRST MPJ HEMI
COATING / SIZE / MM
MATERIAL:



REF XXXXX	LOT XXXXXX	SN XXXXX
QTY 1	MFG Date YEAR-MM-DD	Expiration Date YEAR-MM-DD

Consult IFU

Single Use

Do not use if package is damaged

Caution

Manufactured by

STERILE EO Sterilized using ethylene oxide

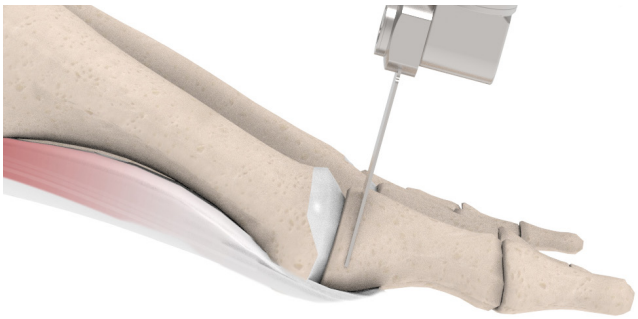
℞ Only Prescription Use Only

Color coded dots indicate implant size and coating

SM PC 17MM	M/S PC 18.5MM	MD PC 20MM	M/L PC 21.5MM	LG PC 23MM
SM NPC 17MM	M/S NPC 18.5MM	MD NPC 20MM	M/L NPC 21.5MM	LG NPC 23MM

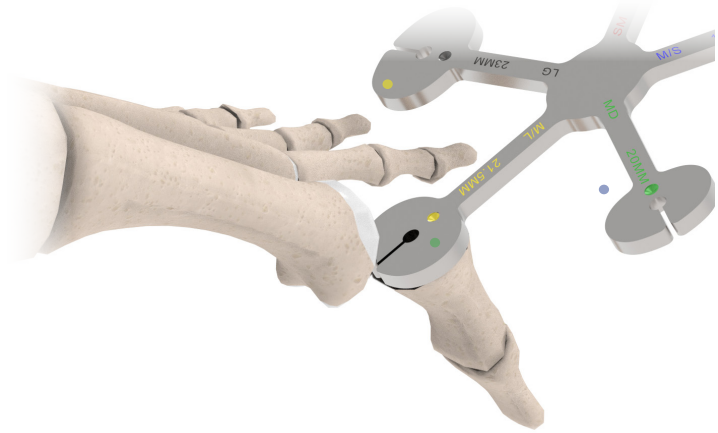
Instructions for Use

The following is an abbreviated technique. Please refer to surgical technique for complete details.

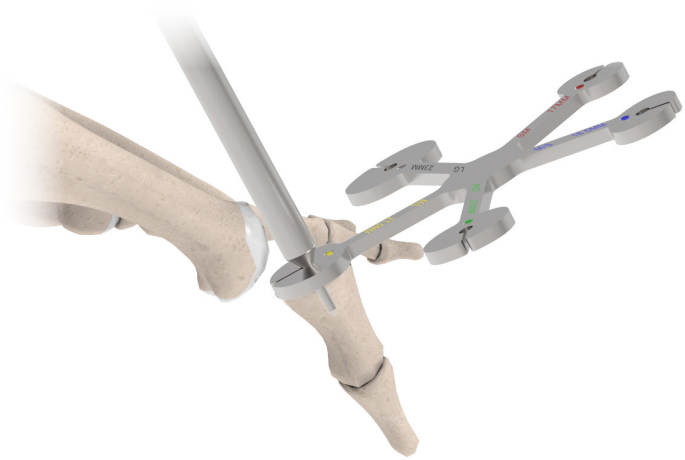


1. Expose the first metatarsophalangeal joint and resect approximately 4 to 6mm off the base of the proximal phalanx.

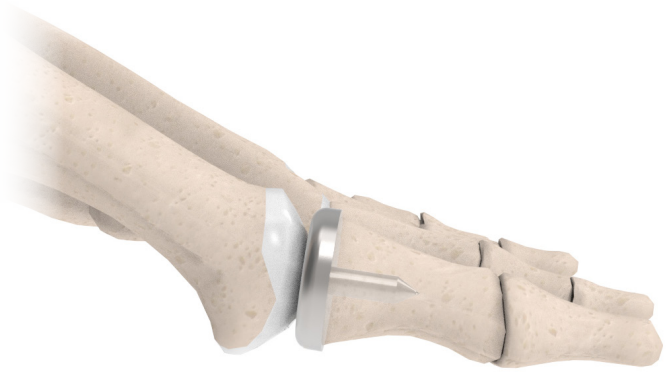
2. Remodel the metatarsal head and remove all abnormal or irregular bone.



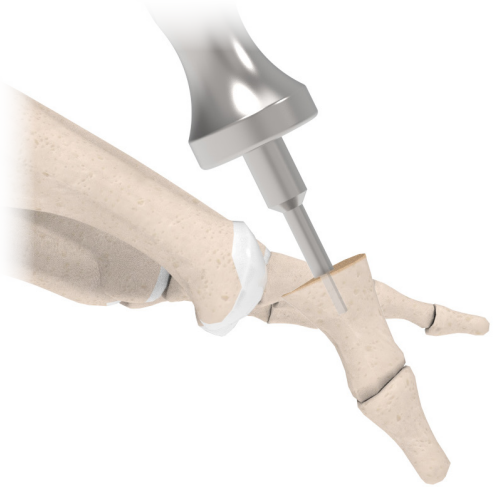
3. Implant selection is made using the 5-star template.



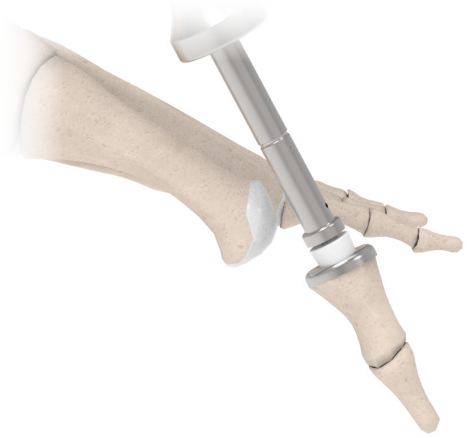
4. Using the 5-star template center hole, insert the trial punch and tap to stop point.



5. The appropriately sized trial implant is now inserted into the hole created by the trial punch. Verification of the correct size is made and the joint is put through normal range of motion.



6. The final impression is created with the toe punch.



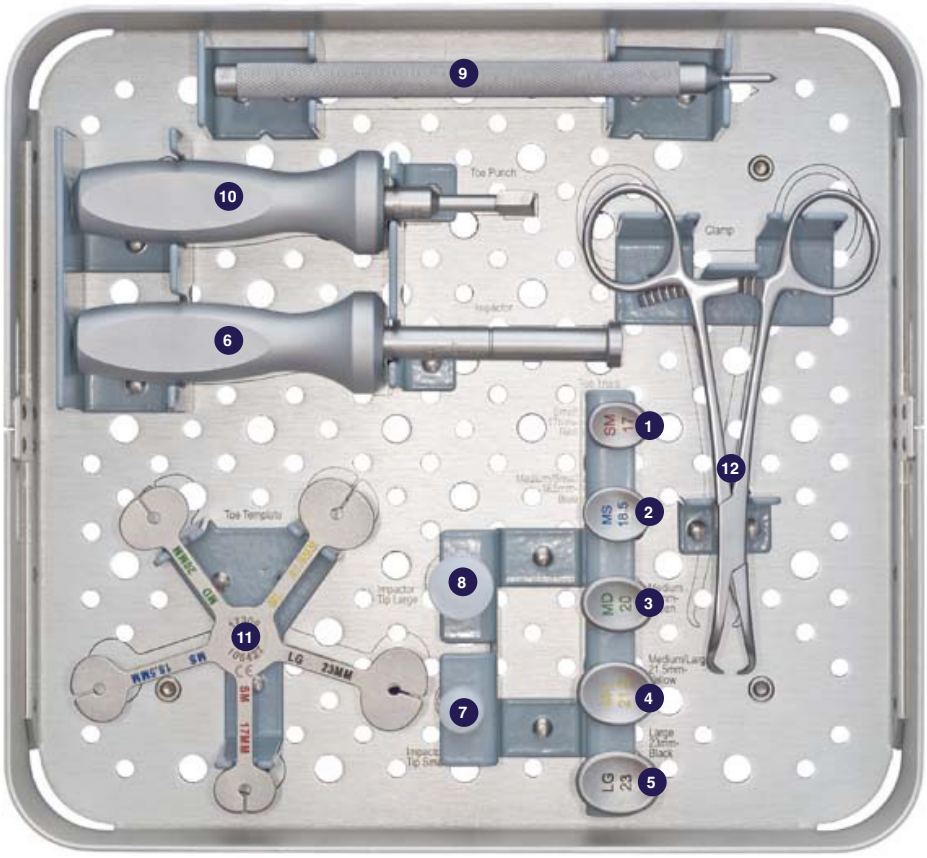
7. Insert the appropriate size sterile packaged implant into the canal. Final seating is performed using the impactor.

Ordering

Item #	Description	Size	Color Code
10412	Cobalt Chrome Porous Coated Small	17mm	Red
17034	Cobalt Chrome Porous Coated Medium Small	18.5mm	Blue
10413	Cobalt Chrome Porous Coated Medium	20mm	Green
14960	Cobalt Chrome Porous Coated Medium Large	21.5mm	Yellow
10414	Cobalt Chrome Porous Coated Large	23mm	Black
10060	Cobalt Chrome Non-Porous Coated Small	17mm	Red
17033	Cobalt Chrome Non-Porous Coated Medium Small	18.5mm	Blue
10061	Cobalt Chrome Non-Porous Coated Medium	20mm	Green
14958	Cobalt Chrome Non-Porous Coated Medium Large	21.5mm	Yellow
10062	Cobalt Chrome Non-Porous Coated Large	23mm	Black
17035	Titanium Porous Coated Small	17mm	Red
17197	Titanium Porous Coated Medium Small	18.5mm	Blue
17036	Titanium Porous Coated Medium	20mm	Green
17037	Titanium Porous Coated Medium Large	21.5mm	Yellow
17038	Titanium Porous Coated Large	23mm	Black
16813	Titanium Non-Porous Coated Small	17mm	Red
17198	Titanium Non-Porous Coated Medium Small	18.5mm	Blue
16814	Titanium Non-Porous Coated Medium	20mm	Green
16815	Titanium Non-Porous Coated Medium Large	21.5mm	Yellow
16816	Titanium Non-Porous Coated Large	23mm	Black

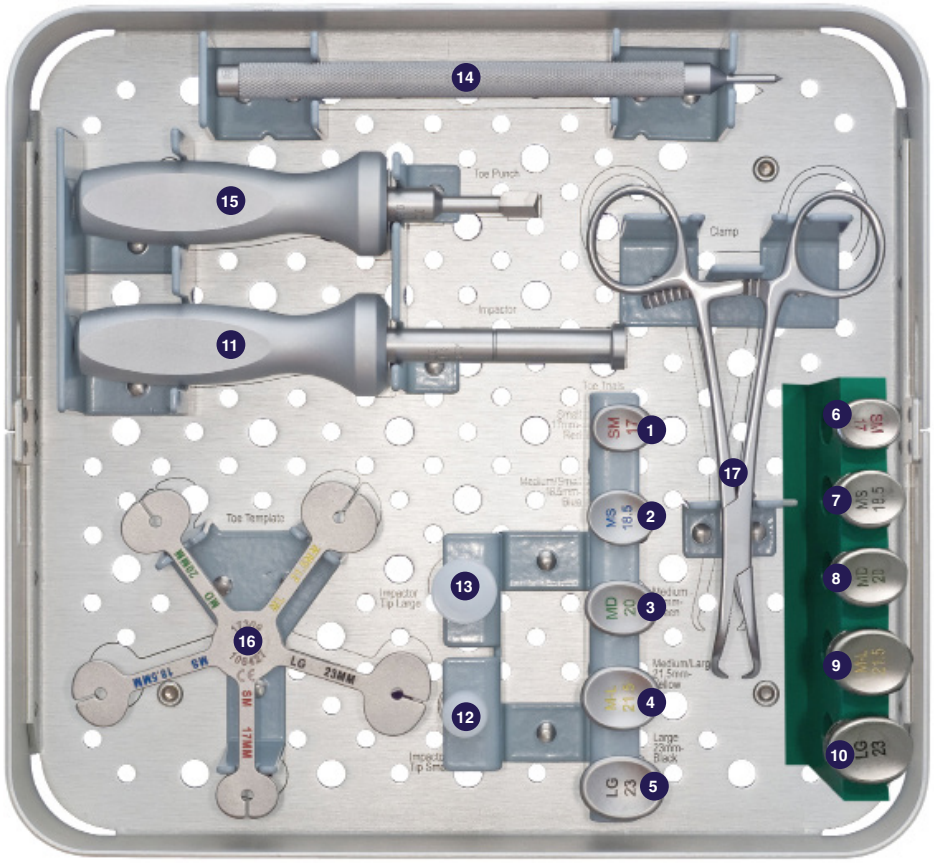
Item #	Description	Size	Color Code
19538	HemiEDGE Implant Small	17mm	Red
19539	HemiEDGE Implant Medium Small	18.5mm	Blue
19540	HemiEDGE Implant Medium	20mm	Green
19541	HemiEDGE Implant Medium Large	21.5mm	Yellow
19542	HemiEDGE Implant Large	23mm	Black

ITEM #	DESCRIPTION	SIZE
16818	Lesser MPJ Hemi	8.00mm
16867	Lesser MPJ Hemi	8.75mm
16819	Lesser MPJ Hemi	9.50mm
16820	Lesser MPJ Hemi	10.25mm
16821	Lesser MPJ Hemi	11.00mm
16822	Lesser MPJ Hemi	11.75mm
16868	Lesser MPJ Hemi	12.50mm
16869	Lesser MPJ Hemi	13.25mm
16870	Lesser MPJ Hemi	14.00mm
17324	Lesser MPJ Hemi Cannulated	8.00mm
17325	Lesser MPJ Hemi Cannulated	8.75mm
17326	Lesser MPJ Hemi Cannulated	9.50mm
17327	Lesser MPJ Hemi Cannulated	10.25mm
17328	Lesser MPJ Hemi Cannulated	11.00mm
17329	Lesser MPJ Hemi Cannulated	11.75mm
17330	Lesser MPJ Hemi Cannulated	12.50mm
17331	Lesser MPJ Hemi Cannulated	13.25mm
17332	Lesser MPJ Hemi Cannulated	14.00mm



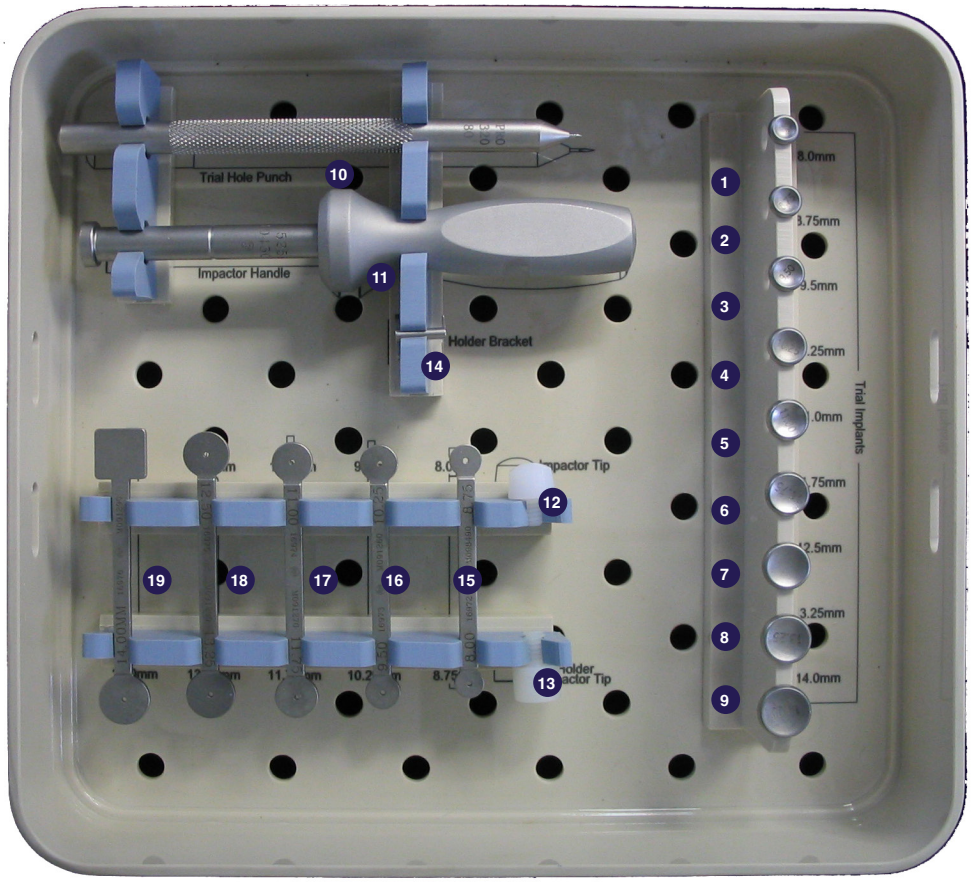
17368 - First MPJ Hemi Complete Kit

Location	Item #	Description
1	12235	MPJ Trial 17mm (SM)
2	17180	MPJ Trial 18.5mm (MS)
3	12236	MPJ Trial 20mm (MD)
4	14959	MPJ Trial 21.5mm (ML)
5	12237	MPJ Trial 23mm (LG)
6	15259	Impactor Handle
7	15256	Impactor Tip SM
8	15257	Impactor Tip LG
9	17786	Trial Punch
10	15112	Toe Punch
11	17309	5-Star Template
12	18100	Towel Clamp



20287- HemiEDGE Complete Kit

Location	Item #	Description
1	12235	MPJ Trial 17mm (SM)
2	17180	MPJ Trial 18.5mm (MS)
3	12236	MPJ Trial 20mm (MD)
4	14959	MPJ Trial 21.5mm (ML)
5	12237	MPJ Trial 23mm (LG)
6	19673	HemiEDGE Trial 17mm (SM)
7	19674	HemiEDGE Trial 18.5mm (MS)
8	19675	HemiEDGE Trial 20mm (MD)
9	19676	HemiEDGE Trial 21.5mm (ML)
10	19677	HemiEDGE Trial 23mm (LG)
11	15259	Impactor Handle
12	15256	Impactor Tip SM
13	15257	Impactor Tip LG
14	17786	Punch
15	15112	Chisel
16	17309	5-Sided Implant
17	18100	Towel Clamp



16979- Lesser Mpj Hemi Complete Kit

Location	Item #	Description
1	16963	Lesser MPJ Trial 8.00mm
2	16964	Lesser MPJ Trial 8.75mm
3	16965	Lesser MPJ Trial 9.50mm
4	16966	Lesser MPJ Trial 10.25mm
5	16967	Lesser MPJ Trial 11.00mm
6	16968	Lesser MPJ Trial 11.75mm
7	16969	Lesser MPJ Trial 12.50mm
8	16970	Lesser MPJ Trial 13.25mm
9	16971	Lesser MPJ Trial 14.00mm
10	16980	Trial Punch
11	15259	Impactor Handle
12	15256	Impactor Tip SM
13	18284	Impactor Tip Flat
14	16977	MPJ Holder Bracket
15	16972	Template 8.00mm/8.75mm
16	16973	Template 9.50mm/10.25mm
17	16974	Template 11.00mm/11.75mm
18	16975	Template 12.50mm/13.25mm
19	16976	Template 14.00mm/Square

Reimbursement

Outpatient Reimbursement		**National Medicare Average**	
CPT Code	Description	Hospital Outpatient	Ambulatory Surgical Center
28291	Hallux rigidus correction w/ cheilectomy, debridement and capsular release first metatarsophalangeal	$6816	$4,644

Physician Reimbursement		National Medicare Average	
CPT Code	Description	RVU	Payment
28291	Hallux rigidus correction w/ cheilectomy, debridement and capsular release first metatarsophalangeal	14.39	$475

HCPCS	Description
C1776	Joint device (implantable)
L8641	Metatarsal joint implant
L8642	Hallux implant

†Payment may vary by location. Prices shown are national averages, based on Medicare's 2024 payments and co-payments. Treatments may include one or more procedures.

The coding and reimbursement information and data provided by BioPro, Inc. is presented for informational purposes only and is not a complete listing of possible codes. This reimbursement information does not constitute a representation or guarantee by BioPro, Inc. and BioPro, Inc. will hold no responsibility for the results or consequences of the use of this information.

FDA Information

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2 2004

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

Re: K041595
Trade/Device Name: BioPro Hemi MP Joint
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: II
Product Code: KWD
Dated: September 7, 2004
Received: September 9, 2004

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/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

OCT 3 0 2012

Re: K121973
Trade/Device Name: BioPro Hemi-Edge Toe System
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: October 10, 2012
Received: October 18, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

References

1. Timothy Voskuijl, MD, Ron Onstenk, MD. Operative Treatment for Osteoarthritis of the First Metatarsophalangeal Joint: Arthrodesis Versus Hemiarthroplasty. The Journal of Foot & Ankle Surgery xxx (2015) 1–4
2. Karin H. Simons, MD, Pieter van der Woude, MD, Frank W.M. Faber, MD, PhD , Paulien M. van Kampen, PhD , Bregje J.W. Thomassen, PhD. Short-Term Clinical Outcome of Hemiarthroplasty Versus Arthrodesis for End-Stage Hallux Rigidus. The Journal of Foot & Ankle Surgery xxx (2015) 1–4
3. Giza E, Sullivan MR. First Metatarsophalangeal Hemiarthroplasty for Grade III and IV Hallux Rigidus Techniques in Foot and Ankle Surgery 4(1):10-17,2005
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6. Roukis TS, Townley, MD. BIOPRO resurfacing endoprosthesis versus periarticular osteotomy for hallux rigidus: short-term follow-up and analysis. Journal of Foot & Ankle Surgery 2003;42(6):350-8
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12. Giza, E., Sullivan, M., Ocel, D., Lundeen, G., Mitchell, M., & Frizzell, L. (2010). First metatarsophalangeal hemiarthroplasty for hallux rigidus. International Orthopaedics, 34(8), 1193–1198. http://doi.org/10.1007/s00264-010-1012-x 13. Garras, D. N., Durinka, J. B., Bercik, M., Miller, A. G., & Raikin, S. M. (2013). Conversion Arthrodesis for Failed First Metatarsophalangeal Joint Hemiarthroplasty. Foot & Ankle International, 34(9), 1227–1232.

BIOLOGICALLY ORIENTED PROSTHESES

BIOPRO

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ISO 13485:2016 CERTIFICATION

intertek™