## 2. 510(k) SUMMARY

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| **Sponsor Name:** | TGM Medical, Inc.<br>5145 Golden Foothill Parkway, Suite 175<br>El Dorado Hills, CA 95762 |
| **510(k) Contact:** | Prakash Pai<br>Phone: (916) 358-8835<br>Email: Prakash.pai63@yahoo.com |
| **Date Prepared:** | January 03, 2013 |
| **Trade Name:** | MILESTONE Revision Knee System |
| **Common Name:** | Revision knee prosthesis |
| **Classification Name:** | Knee joint patellofemorotibial metal/polymer/metal semiconstrained cemented prosthesis (21 CFR 888.3560, Class II device, Product Code JWH) |

**Device Description:**
The MILESTONE Revision Knee System (MRKS) is a semi-constrained, cemented knee prosthesis designed for either primary or revision total knee arthroplasty. The MRKS contains left and right configurations of a femoral component and a fixed-bearing tibial component, in addition to accessory components including stems, augments, screws, pegs, a taper plug, and a baseplate plug. The femoral component and tibial baseplate employ modularity for stem and augment attachment.

The MRKS femoral component is manufactured from cast cobalt chrome alloy. It is offered in six sizes (1-6) and is designed to articulate with the MRKS ultracongruent tibial insert and the MILESTONE Knee System (MKS) all poly patellar component (K112285). The MRKS femoral component is not designed to articulate with the MKS posterior stabilizing (PS) tibial insert (K112285) or any condylar constrained tibial components. The MRKS box profile is thicker than the MKS femoral component to accommodate increased bone loss.

The MRKS tibial component consists of two parts to be assembled at the time of surgery: a tibial baseplate and an ultracongruent (PCL substituting) tibial insert. The baseplate is manufactured from cast cobalt chrome alloy and is designed with an identical locking mechanism as the MKS tibial baseplate (K112285). The baseplate is offered in seven sizes (0-6) and is designed to accommodate the MRKS ultracongruent insert when used with the MRKS femoral component or the MKS PS tibial insert (K112285) when used with the MKS PS femoral component (K112285). The MRKS tibial baseplate is thicker than the MKS baseplate to accommodate increased bone loss. The MRKS insert is manufactured from ultra-high molecular weight polyethylene (UHMWPE) and is designed with an identical locking mechanism, thickness, and size range as the MKS PS insert.

The MRKS accessory components are manufactured from Titanium alloy. The stems are available in three lengths (80, 110, and 150mm) and seven diameters (10-22mm). They employ a male 12/14 Morse taper for attachment to the CRKS femoral component or tibial baseplate. The taper plug is available in one size and is intended for use when a stem is not desired. The taper plug employs an identical male taper as the stem. The augments are available in left and right configurations, and are offered in a range of sizes to accommodate all sizes of the MRKS femoral components and tibial baseplates. Femoral augments are split into distal and posterior segments, each available in 5mm thicknesses. Tibial augments are available in 5mm and 10mm thicknesses. The pegs are offered in three sizes (short, medium, and long). Screws are offered in two sizes (short and long). The baseplate plug is offered in one size. The pegs and screws are designed for mechanically attaching the augments to their respective implants. Pegs also aid in stabilizing the implant post-operatively and are designed to fill the distal augments holes of the femoral component and augment holes of the tibial baseplate when augments are not desired. The baseplate plug is designed to fill the baseplate augment holes when pegs and augments are not desired.

**Indications for Use:**

A. Primary intervention of rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, and/or avascular necrosis of the femoral condyle.
B. Post-traumatic loss of joint configuration (particularly when there is patellofemoral erosion, dysfunction, or prior patellectomy).
C. Failed osteotomy or unicompartmental replacements.
D. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.
E. The salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery.
F. Moderate valgus, varus, or flexion deformities.

All MRKS femoral components and tibial baseplates are intended for cemented use only. All MRKS stems are intended uncemented use.

**Substantial Equivalence:**

***Technological Characteristics/Substantial Equivalence:***

Consensus Orthopedics, Inc. (COI) licensed the previously cleared Consensus Revision Knee System (CRKS) components (K100542) and the Consensus Knee System (CKS) ultracongruent (i.e. PCL substituting) tibial inserts (K953443) to TGM Medical for use as the MILESTONE Revision Knee System (MRKS). These predicate knee system components are identical to the respective MRKS components in material, geometry, and indications. The MRKS femoral component is compatible with the previously cleared Milestone Knee System (MKS) round all-poly patella (K112285); however it is not compatible with the MKS posterior stabilizing (PS) tibial insert (K112285). The MRKS tibial baseplate is compatible with the MKS PS tibial insert when articulating with the MKS PS femoral component (K112285). The MRKS ultracongruent tibial insert is compatible with the MKS tibial baseplate (K112285); however it is not compatible with MKS PS femoral component (K112285). Because the subject MRKS components employ

the same materials, technological characteristics, and indications as their predicate devices, the MRKS components are substantially equivalent to legally marketed predicates (Table 2.1).

*Table 2.1:* Legally marketed predicates to which substantial equivalence is claimed.

| 510(k) Number | Trade Name | 510(k) holder | 510(k) Clearance |
|---|---|---|---|
| K953443 | Consensus PCL Substituting Tibial Insert | U.S. Medical Products, Inc. | 04/26/1996* |
| K100542 | Consensus Revision Knee System | Consensus Orthopedics, Inc. | 06/24/2010 |
| K112285 | Milestone Knee System | TGM Medical, Inc. | 11/04/2011 |

Notes: *Cleared prior to the purchase of U.S. Medical Products by Hayes Medical in 1996 and prior to the change in company name from Hayes Medical to Consensus Orthopedics in 2008.

**Non-Clinical Performance Data:**

COI provided rights to reference their 510(k)s and supporting performance testing. The MRKS was evaluated using a Failure Modes and Effects Analysis (FMEA). Because the MRKS components employ identical geometry and material characteristics as those employed by their respective predicate CRKS and CKS components, non-clinical bench testing and analyses were provided for these predicate components to validate the safety and effectiveness of the MRKS. No further testing on MRKS components was necessary.

**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

May 3, 2013

TGM Medical, Inc.
% Mr. Prakash Pai
Vice President, Global Quality & Regulatory Affairs
5145 Golden Foothill Parkway, Suite 175
El Dorado Hills, California 95762

Re: K130084
Trade/Device Name: MILESTONE Revision Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: JWH
Dated: February 5, 2013
Received: February 6, 2013

Dear Mr. Pai:

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,

Erin D. Keith

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

Enclosure

## 1. INDICATIONS FOR USE STATEMENT

**510(k) Number** (if known): K130084

**Device Name:** MILESTONE Revision Knee System (MRKS)

**Indications for Use:**

A. Primary intervention of rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, and/or avascular necrosis of the femoral condyle.
B. Post-traumatic loss of joint configuration (particularly when there is patellofemoral erosion, dysfunction, or prior patellectomy).
C. Failed osteotomy or unicompartmental replacements.
D. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.
E. The salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery.
F. Moderate valgus, varus, or flexion deformities.

All MRKS femoral components and tibial baseplates are intended for CEMENTED USE ONLY.
All MRKS stems are intended for UNCEMENTED USE.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) AND/OR Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices