DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 17, 2014

MatOrtho Limited
% Mr. Marcos Velez-Duran
President
M-Squared Associates Incorporated
815 King Street
Alexandria, Virginia 22314

Re: K140222
Trade/Device Name: Saiph® Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: October 9, 2014
Received: October 14, 2014

Dear Mr. Velez-Duran:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Lori A. Wiggins -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K140222

Device Name
Saiph® Knee System

Indications for Use *(Describe)*

The Saiph® Knee System is intended for cemented only in the U.S. It is intended for single use in total knee arthroplasty surgery for the reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease resulting from osteoarthritis, traumatic arthritis and avascular necrosis;
2. Inflammatory degenerative joint disease including rheumatoid arthritis;
3. Correction of varus, valgus, or post traumatic deformity;
4. Correction or revision of unsuccessful osteotomy or arthrodesis;
5. Revision procedures where other treatments or devices have failed; and
6. Treatment of fractures that are unmanageable using other techniques.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

| **Submitter Information** | |
|---|---|
| Name | **MatOrtho Limited** |
| Address | 13 Mole Business Park<br>Randalls Road<br>Leatherhead<br>Surrey<br>KT22 7BA<br>United Kingdom |
| Phone number | +44 (0)1372 224 200 |
| Fax number | +44 (0)1372 366 343 |
| Establishment Registration Number | 9035148 |
| Name of contact person | Marcos Velez-Duran |
| Date prepared | October 8, 2014 |
| **Name of device** | |
| Trade or proprietary name | Saiph® Knee System |
| Common or usual name | Knee Prosthesis |
| **Classification name** | Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (Class II) |
| **Classification panel** | Orthopedic |
| **Regulation** | 21 CFR 888.3560 |
| **Product Code(s)** | 87JWH |
| **Legally marketed device(s) to which equivalence is claimed** | K020214 - Medial Rotation Knee™ (MRK) System (JWH)<br>K023211 - *NexGen*® Complete Knee Solution Cruciate Retaining (CR)-Flex Femoral Components (JWH)<br>K003910 - *NexGen*® Complete Knee Solution Crosslinked Polyethylene Cruciate Retaining (CR) Articular Surface Components (JWH)<br>K963148 - *NexGen*® Complete Knee Solution (JWH)<br>K031729 - *Triathlon*® PS Knee (JWH)<br>K935080 – *Insall Burstein II*<br>K931466 – PFC Modular Total Knee System<br>K946088 - *Genesis*® PS Knee |

| | |
|---|---|
| | K932070 - *Duracon*® Constrained PS Knee |
| **Reason for 510(k) submission** | New device |
| **Device description** | The Saiph® Knee System is used in total knee replacement to replace articulating surfaces of the femur, tibia and patella. The device is intended for cemented fixation only. The patella is optional depending upon surgeon preference and is cemented use only. The femoral and tibial tray components are made from cast cobalt chrome. The tibial bearing and patella components are made from ultra-high molecular weight polyethylene (UHMWPE). The femoral component is highly polished to articulate with the tibial bearing. All devices are gamma irradiated. |
| **Intended use of the device** | Cemented total joint replacement intended to replace diseased or severely worn articulating surfaces of the knee joint. |
| **Indications for use** | The Saiph® Knee System is intended for cemented only in the U.S. It is intended for single use in total knee arthroplasty surgery for the reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:<br>1. Non-inflammatory degenerative joint disease resulting from osteoarthritis, traumatic arthritis and avascular necrosis;<br>2. Inflammatory degenerative joint disease including rheumatoid arthritis;<br>3. Correction of varus, valgus, or post traumatic deformity;<br>4. Correction or revision of unsuccessful osteotomy or arthrodesis;<br>5. Revision procedures where other treatments or devices have failed; and<br>6. Treatment of fractures that are unmanageable using other techniques. |

**Summary of the technologies**

The Saiph® Knee System is comprised of the multiple components including femorals, tibial trays and bearings, and patella, as well as instrumentation.

The technological characteristics are the same as the predicate devices (K020214, K023211, K003910, K963148 and K031729) in terms of design, materials, and principle of operation with the exception of the slight modifications outlined in this 510(k) submission.

The femur, tibia and patellar components utilize the identical manufacturing processes as the predicate, Medial Rotation Knee™ (MRK) System (K020214). This includes the same cemented (stippled) surface and "barb" locking mechanism used for the tibial tray and tibial bearing. Non-clinical tests were used to characterize the physical aspects of the design and to demonstrate substantial equivalence to the predicate devices. A summary of physical testing is given in the Performance Data (Non-clinical) section below. Physical testing is considered acceptable and equivalent to predicate devices. Clinical evidence of the Saiph is available in Australia and Europe and the device has been in use since 2009. A summary of Clinical Data is given below.

**PERFORMANCE DATA**

**SUMMARY OF NON-CLINICAL TESTS**

**Performance Test Summary-New Device**

The Saiph® Knee System has been evaluated for tibial tray fatigue strength, insert locking mechanism strength, tibiofemoral range of motion, tibiofemoral range of constraint, patellofemoral range of constraint, tibiofemoral contact areas/contact stress and patellofemoral contact area and contact stress. The testing confirms that the Saiph® Knee System is capable of withstanding loads in excess of those expected *in vivo* and is substantially equivalent to the competitive legally marketed knee systems.

**SUMMARY OF CLINICAL TESTS**

Clinical usage in Europe (England and Belgium) and Australia validated that the specific surgical instruments included with this system meet user needs.

A total of 127 procedures have been registered by the National Joint Registries in the UK. Maximum follow up is 4.8 years (minimum 1.6 years). There have been no reports of revisions.

A multi-center, post-market study is ongoing in the Australia and the UK with 282 implants. The implants have been followed for average 1.9 years (range 0.6 to 5 years). There have been 3 revisions.

There have been no device related failures.

**CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA**

The Saiph® Knee System was found to be substantially equivalent to the predicate devices based on non-clinical testing. Clinical data from the National Joint Registry in the UK and data from a post-market clinical study being conducted in Australia and the UK show that the Saiph® Knee System is safe and effective. There have been no device related failures.