K081023 #1 of 3

Medacta International

OCT 22 2008

510(k) Summary

Manufacturer: MEDACTA International SA
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Contact Person: Ms. Natalie J. Kennel
Consultant
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Date Prepared: July 7, 2008

DEVICE INFORMATION

Trade/Proprietary Name: Evolis Total Knee System
Common Name Total Knee Prosthesis
Classification Name: Knee joint patellofemorotibial metal/polymer/metal semiconstrained cemented prosthesis, 21 CFR 888.3560, product code JWH

Predicate Devices:
K072281, NexGen® Prolong All-Poly Patella;
K072619, NexGen® Complete Knee Solution LPS-Flex Porous Femoral Component;
K070981, Search Evolution (LC) Total Knee System,
K060722, NexGen® Complete Knee Solution Ultracongruent (UC-Flex) Fixed Bearing Articular Surface Component;
K031061, NexGen® Porous, Uncemented Femoral and Tibial Baseplate Components;
K991581, NexGen® Complete Knee Solution Legacy® Posterior Stabilized (LPS), LPS-Flex Fixed Bearing Femoral and Articular Surface Components;

K963148, NexGen® Complete Knee Solution Fluted Stemmed Tibial Component.
K960279, NexGen® Legacy PS (L-PS) and NexGen® CCK (L-CCK)
K951185, NexGen® Total Knee Solution 9 mm Tibial Articular Surface

Product Description:
The Evolis Total Knee System is a tricompartmental fixed bearing total knee prosthesis comprised of femoral, patellar, and tibial components with ultra-high molecular weight polyethylene articular inserts. The femoral components are offered in left and right sizes in a standard and a posterior stabilized design of six sizes. The tibial baseplates are offered in six sizes. The tibial inserts are offered in three styles: standard, posterior-stabilized and ultra-congruent. Each of the three styles is offered in six sizes, corresponding to the tibial base plate sizes, in five thicknesses from 9 -19 mm each. The patellar components are offered in two options: an inset patella and a resurfacing patella. The inset patella is offered in the three sizes and the resurfacing patella is offered in four sizes. The femoral components and the tibial base plates are offered in coated options with a plasma spray titanium coating.

Indications for Use:
The Evolis Total Knee System is designed for cemented use in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.

This knee replacement system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis
- avascular necrosis of femoral condyle
- post traumatic loss of joint configuration
- primary implantation failure.

Performance Testing
No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act. Performance testing of the Evolis Total Knee System was conducted in accordance with various international standards and FDA guidance documents.

The Evolis Total Knee System was tested as part of design verification to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the above standards and guidance. The testing was conducted on the worst case component size and option/design. The testing met all acceptance criteria and verifies that performance of the Evolis Total Knee System is substantially equivalent to the predicate devices.

K080545

Conclusion:

The data and information provided in this submission support the conclusion that the Evolis Total Knee System is substantially equivalent to its predicate devices with respect to indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MEDACTA International SA
% NJK & Associates, Inc.
Ms. Natalie J. Kennel
13721 Via Tres Vista
San Diego, California 92129

OCT 22 2008

Re: K081023
Trade/Device Name: Evolis Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: October 13, 2008
Received: October 15, 2008

Dear Ms. Kennel:

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 Statement

510(k) Number (if known): K081023

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

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

510(k) Number K081023