K023667 P1/1

Amended 510(k) Summary

Date
November 26, 2002

DEC 2 4 2002

Submitter
PLUS ORTHOPEDICS
6055 Lusk Blvd
San Diego, CA 92121

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-4694

Common name
Hinged knee

Classification name
Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer (per 21 CFR section 888.3510)

Equivalent Device
The RT-PLUS and RT-PLUS Knee systems are equivalent to the RT-PLUS Knee (K013340) and RT-PLUS Modular Knee (K003504).

Device Description
The RT-PLUS Knee and RT-PLUS Modular Knee are hinged tri-compartmental prostheses with femoral, tibial, and patella components and are of the cemented total condylar type. They are intended to be used for replacement of the total knee joint in which significant bone loss and/or ligamentous deficiencies have occurred due to tumors, trauma, infections, revision or connective tissue disorders. Both of these knee systems provide joint stability when any or all of the following structures are non-functional: MCL, LCL, PCL, ACL or the illiotibial band. Both systems include polyethylene tibial augmentation blocks. The Modular knee includes modular femoral and tibial stems.

The modifications described in this submission include:
1. Changes to the outside surfaces of the ultra high molecular weight polyethylene (ASTM F648) augmentation blocks and addition of blocks for Size 2 and 10 tibial baseplates. (Original cleared on K003504)
2. Additional titanium alloy (ASTM F136) stem sizes (Original cleared on K003504)
3. Addition of CoCrMo (ASTM F75) augmentation blocks
4. Changes to femoral and tibial baseplate components to accept CoCrMo blocks (Original cleared on K003504)
5. Addition of size 2 and 10 femoral and tibial baseplate components (Non-modular cleared on K013340)

Intended Use
The RT-PLUS Knee System is indicated for use for replacement of the total knee joint in which significant bone loss and/or ligamentous deficiencies have occurred due to tumors, trauma, infections, revision or connective tissue disorders. RT-PLUS Modular Knee provides joint stability when any or all of the following structures are non-functional: MCL, LCL, PCL, ACL or the illiotibial band.

Summary of Technological Characteristics Compared to Predicate Device
The RT-PLUS and RT-PLUS Modular Knee systems with modifications have the same indications, materials and fundamental scientific technology as the RT-PLUS Knee (K013340) and RT-PLUS Modular Knee (K003504).

Summary Nonclinical Tests
ISO 14789-1 "Implants for surgery -- Total knee-joint prostheses -- Part 1: Determination of endurance properties of knee tibial trays" was complied with.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 4 2002

PLUS Orthopedics
c/o Mr. J.D. Webb
1001 Oakwood Road
Round Rock, Texas 78681

Re: K023667
Trade/Device Name: RT-PLUS Solution and RT-PLUS Modular Solution Knee
Regulation Number: 21 CFR §888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: II
Product Code: KRO
Dated: November 29, 2002
Received: December 2, 2002

Dear Mr. Webb:

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known): K023667

Device Name: RT-PLUS & RT-PLUS Modular Knee Systems

Indications for Use:

RT-PLUS™ & RT-PLUS™ Modular Knee Systems
Indications for Use

The RT-PLUS Knee System is a tricompartmental rotating hinged prosthesis of the total condylar type. The system consists of femoral, tibial and patellar components. It is indicated for use for replacement of the total knee joint in which significant bone loss and/or ligamentous deficiencies have occurred due to tumors, trauma, infections, revision or connective tissue disorders. RT-PLUS Modular Knee provides joint stability when any or all of the following structures are non-functional: MCL, LCL, PCL, ACL or the illiotibial band.

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

Concurrence of CDRH, Office of Device Evaluation (ODE
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Prescription Use X
(per 21 CFR 801.109)OROver-the-Counter Use ____(Optional format 1-2-96) _____

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

510(k) Number K023667