510(k) Summary of Safety and Effectiveness

K101859

OCT 13 2010

A. General Information

1.	*Submitter's Name:*	Rizzoli Ortopedia, S.p.A.
2.	*Submitter's Address:*	Via C. Battisti 44 - 40054 BUDRIO (BO) - ITALIA
3.	*Submitter's Telephone:*	+390516930735
4.	*Contact Person:*	Diane C. Tiernan, MS RAC Consultant McCormick LifeScience Consultants 58A Bates Road Watertown, MA 02472
5.	*Date Prepared:*	July 1, 2010
6.	*Registration Number:*	not yet assigned

B. Device

1.	*Name:*	Rel-k
2.	*Trade Name:*	Rel-k
3.	*Common Name:*	External Limb Prosthetic Component (Knee)
4.	*Classification Name:*	External Limb Prosthetic Component (Knee)
5.	*Product Code:*	89 ISY
6.	*Class:*	I, Exempt
7.	*Regulation Number:*	890.3240

C. Identification of Legally Marketed Devices

1.	*Name:*	C-Leg (3C100)
2.	*510(k) Number:*	K991590
3.	*Date Cleared:*	July 8, 1999

D. Description of the Device

The Rel-k is an artificial limb prosthesis indicated for individuals that have undergone a trans-femoral amputation. The Rel-k is intended to replace a missing or deformed limb and functions in both normal/standing (static) and dynamic walking.

The Rel-k consists of:

- Pyramidal Head
- Angular Sensor
- Force sensor
- Servo assisted Hydraulic Damper (MPC damper)
- Removable Battery and electronics compartment
- Carbon Fiber Shell (outer casing)
- Attachment for a standard 30mm diameter tube.

E. Intended Use Statement

The Rel-k is prosthetic knee, important element of a lower limb prosthesis, a medical device that is used to replace a missing or deformed limb in both static and dynamic deambulation functions.

F. Technological Characteristics Summary

The Rel-k is substantially equivalent to the Otto Bock C-Leg (C100), a Class I Exempt Device per 21CFR Part 890.3420.

Differences that exist between the Rel-k and the C-Leg (C100) devices related to the technical specifications, physical appearance and design does not raise new questions of safety and effectiveness; and demonstrates that the Rel-k device is at least as safe and effective as the legally marketed Otto Bock C-Leg (C100) device.

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

Rizzoli Ortopedica S.P.A.
% McCormick LifeScience Consultants
Ms. Diane C. Tiernan, MS RAC
Consultant
58A Bates Road
Watertown, Massachusetts 02472

OCT 13 2010

Re: K101859
Trade/Device Name: Rel-k Artificial Limb Prosthesis
Regulation Number: 21 CFR 890.3420
Regulation Name: External limb prosthetic component
Regulatory Class: Class I
Product Code: ISY
Dated: September 29, 2010
Received: September 30, 2010

Dear Ms. Tiernan:

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

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,

For Director

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

Indications for Use

K101859

510(k) Number (if known):

OCT 13 2010

Device Name: Rel-k Artificial Limb Prosthesis

Indications For Use:
REL-k is a prosthetic knee, important element of a lower limb prosthesis, a medical device that is used to replace a missing or deformed limb in both static and dynamic deambulation functions

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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