

JUL 8 1999

Otto Bock

ORTHOPEDIC INDUSTRY, INC.

K991590

**510(k) SUMMARY
of
SAFETY and EFFECTIVENESS**

A. General Information

1. *Submitter's Name:* Otto Bock Orthopedic Industry, Inc.
2. *Address:* 3000 Xenium Lane North
Minneapolis, MN 55441
3. *Telephone:* 612-553-9464
4. *Contact Person:* John Hendrickson
5. *Date Prepared:* May 6, 1999
6. *Registration Number:* 2182293

B. Device

1. *Name:* C-LEG (3C100)
2. *Trade Name:* C-LEG (3C100)
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

A COMPANY OF THE OTTO BOCK GROUP

Otto Bock Orthopedic Industry, Inc.
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C. Identification of Legally Marketed Devices

1. *Name:* 3C1
2. *K Number:* Exempt
3. *Date Cleared:* Exempt

D. Description of the Device

C-LEG (3C100) is a microprocessor-controlled knee joint system with hydraulic stance and swing phase control. The C-LEG immediately adapts to different walking speeds and provides knee stability.

The C-LEG (3C100) is recommended for lower limb amputees weighing up to 110 kg (220 pounds) who have a moderate (level 2 or 3) functional level. It is a monocentric knee joint composed of:

- Carbon Fiber Frame
- Hydraulics with Servo Motor
- Electronics
- Distal Tube Clamp
- Upper Joint
- Shin Tube Adapter

Components of the C-LEG (3C100) are the following:

- 3C87 Electronic Knee Joint
- 2R90 Tube Adapter or
- 2R91 Tube Adapter with Torsion Adapter
- 4R57 Rotation Adapter

Accessories are the following:

- 757L17 Charging Device
- 757L16 Power Unit
- 1D10, 1D25, 1A30 Prosthetic Foot
- 3S26 Foam Cover
- 4X70 Slider Software
- 4X72 Extension Cable
- 4X71 PC Interface
- 4R302 Transportation Case

E. Intended Use Statement

The C-LEG (3C100) is intended for use in the fitting of lower limb prostheses. It can be used by highly mobile individuals as well as those who need additional stance stability.

F. Technological Characteristics Summary

The C-LEG (3C100) is substantially equivalent to Otto Bock's 3C1, a Class I Exempt Device according to 21 CFR Part 890.3420.

Differences that exist between these devices, relating to technical specifications, physical appearance and design, do not affect the relative safety and effectiveness of the C-LEG (3C100).



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Hendrickson
President
Otto Bock Orthopedic Industry, Inc.
3000 Xenium Lane North
Minneapolis, Minnesota 55441

Re: K991590
Trade Name: C-LEG (3C100)
Regulatory Class: II
Product Code: ISW and KFX
Dated: May 6, 1999
Received: May 7, 1999

Dear Mr. Hendrickson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895.

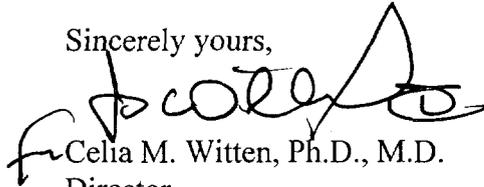
A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. John Hendrickson

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a large, stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K991590

Device Name: C-LEG (3C100)

Indications for Use:

- Fitting of lower limb prosthesis
- Highly mobile individuals and/or individuals who need stance stability

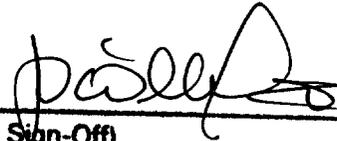
PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

OR

OVER-THE-COUNTER USE _____
(optional Form 1-2-96)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K99159