Otto Bock
HEALTH CARE

K032833

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

QUALITY FOR LIFE

North American Headquarters
Two Carlson Parkway N., Suite 1C
Minneapolis, MN 55447-4467
Phone 1.800.328.4058
Fax 1.800.655.4963

Customer Support & Distribution Center
14630 28th Avenue North
Minneapolis, MN 55447-4821
Phone 1.800.328.4058
Fax 1.800.962.2549

Technical Center
14800 28th Avenue North, Suite 1
Minneapolis, MN 55447-4873
Phone 1.800.795.8846
Fax 1.800.810.7994

Florida Area Fabrication Center
755 Clay Street
Winter Park, FL 32789
Phone 1.800.354.5418
Fax 1.407.599.7999

Ohio Area Fabrication Center
84 Westpark Road
Centerville, OH 45459
Phone 1.937.432.0082
Fax 1.937.432.0087

Utah Design & Manufacturing Center
3820 W. Great Lakes Drive
Salt Lake City, UT 84120-7205
Phone 1.801.956.2400
Fax 1.801.956.2401

Minnesota Design & Manufacturing Center
820 Sundial Drive
Waite Park, MN 56387
Phone 1.800.688.4832
Fax 1.320.251.0110

Customer Satisfaction Hotline
1.877.OBSOLVE
1.877.627.6583

www.ottobockus.com

A. General Information

1.	*Submitter's Name:*	Otto Bock Health Care, LP
2.	*Address:*	Two Carlson Parkway, Suite 100 Minneapolis, MN 55447-4467
3.	*Telephone:*	763-553-9464
4.	*Contact Person:*	Bert Harman
5.	*Date Prepared:*	June 25, 2003
6.	*Registration Number:*	2182293

B. Device

1.	*Name:*	MyoSystem with Customizing
2.	*Trade Name:*	MyoSystem with Customizing
3.	*Common Name:*	MyoSystem with Customizing
4.	*Classification Name:*	External Limb Prosthetic Component
5.	*Product Code:*	GXY
6.	*Class:*	II (2)
7.	*Regulation Number:*	882.1320

C. Identification of Legally Marketed Devices

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

D. Description of the Device

The MyoSystem with Customizing is an adult external electric upper extremity system which allows the CPO to adjust all relevant parameters of the control of an external powered upper extremity prosthesis by a Personal Computer (PC).

The system allows the connection of the control of a prosthesis with a PC by serial communication. A PC Software program allows the monitoring of how the patient performs with the prosthesis and enables the practitioner to change the control parameters according to the patient's needs.

In addition, the practitioner can do the same program changes between control programs of a component as he/she can do by changing a colored coding plug. As it is a much faster process to change a program by the click of a button rather than to dismantle the prosthesis to gain access to the coding plug of a component, there is less disruption in the fitting process. This makes it less tiring for the patient and practitioner.

As this system allows only additional adjustments to the existing adjustment possibilities by dials, there is no program change in the components. The same components which are used by the current conventional adjustment process are used with the adjustment process by CUSTOMIZING.

The MyoSystem with Customizing is composed of the following parts:

MyoBoy	757M10
MyoBoy, Test adapter, Infrared cable	757P23
MyoBock System	
EnergyPack	757B20
Li-Ion battery charger	757L20
System Electric Greifer DMC plus	8E33=8X047108
Electric wrist rotator	10S17
Ergo arm electronic plus	12K50=50-1
SensorHand	8E38=5-L7¾
Transcarpal Hand Digital Twin	8E44=7-L7¾
Four channel processor II	13E195
Adjustment cap	13E196
2 x Myobock-Elektrode 228 (Electrode 60Hz)	13E125=60
2 x Myobock-Elektrode 392 (Electrode 60Hz)	13E68=60
Distributor	13E68190
Battery connection cable	13E188=200
Coaxial plug	9E169

3 x Electrode cable for 13E68	3E48=G800
Electrode cable for 13E125	3E129=G1000
Lamination ring	10S1=50
Coding Plug set	13E182
Coupling piece	none
Battery mounting set	757Z184=1
MyoCom	757T11
MyoCom hardware	757T9
Myo simulator	757T10
Light wave cable	519K27=430
Serial port converter	519K28
PC adaptor	none
Connection cable MyoCom-MyoBoy	757P37
Connection cable MyoCom-battery mounting set	757P38
Battery mounting set for EnergyPack	757B20
Battery mounting set for EnergyPack	757P21
Software / Instructions / Manuals / Customizing	
Product Component	Revision
Myo Soft	Rev. 1222H, Update Rev. 12222K
Myosoft Customizing	Rev. 1.0, Rev. 2.X
Customizing	Rev. D1 (Beta-review), Rev. 2.0.3, Rev.2.1.1
Training Instructions Customizing (Powerpoint presentation)	

E. Intended Use Statement

The MyoSystem with Customizing is intended for adult(s) who require an external electric upper extremity system.

F. Technological Characteristics Summary

The MyoSystem with Customizing is substantially equivalent to Otto Bock's MyoSystem, 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 MyoSystem with Customizing.

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

JUN - 3 2010

Otto Block Health Care, LP
% Mr. Bert Herman
2 Carlson Pkwy. Suite 100
Minneapolis, Minnesota 55447

Re: K032833
Trade/Device Name: Myosystem with Customizing
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY, IQZ
Dated: June 25, 2003
Received: September 11, 2003

Dear Mr. Herman:

This letter corrects our substantially equivalent letter of September 23, 2003.

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 (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 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.

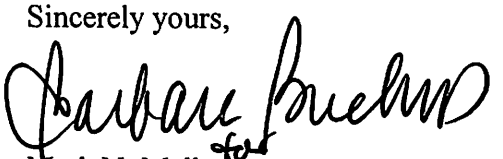
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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,



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

510(k) Number: K032833

Device Name: MyoSystem with Customizing

Indications for Use:

- Adult External Electric Upper Extremity System

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K032833