Legacy Medical, Inc.

Legacy Medical, Inc.
9039 Horizon Drive, Shakopee, MN 55379
Tel: 952-322-7240 Fax: 866-498-5854
Web www.legacy-medical.com

IV. 510(k) Summary

Submitter: Legacy Medical, Inc.
9039 Horizon Drive
Shakopee, MN 55379

OCT 17 2013

Date: March 27, 2013

Contact Person: Debra Robertson, President
Tel: 952-322-7240

Name of Device:

Classification Name:	Cuff, Blood Pressure CFR 870.1120
Common Name:	Non-invasive blood Pressure Cuff
Review Panel:	Cardiovascular
Classification:	Class II
Product Code:	DXQ
Proprietary Name:	Legacy Medical Blood Pressure Cuff

Predicate Devices:

Device	Manufacturer	510(k)
Critikon Soft-Cuf Blood Pressure Cuff	GE Healthcare	K974080
Disposa-Cuff Blood Pressure Cuff	Crest Medical Equipment	K790810
Surgi-Cuff	Ethox Corporation	K883977
Cuff-Able Blood Pressure Cuff	Vital Signs, Inc	K911213
Statcorp Disposable Blood Pressure Cuff	Statcorp, Inc	K940214
Technicuff	Technicuff Corp.	K942259

Device Description:

Per CFR 870.1120, a blood pressure cuff is a device that has an inflatable bladder within, or integral to, an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with an appropriate measuring device to determine a subject's blood pressure.

The Legacy Medical Blood Pressure Cuff comprises a soft inelastic sleeve with an integrated inflatable bladder that is wrapped around the patient's limb and

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III. Statement of Indications for Use

Indications for use:
510(k) number: Pending
Device name: Legacy Medical Blood Pressure Cuff
Indications for use:

The Legacy Medical Blood Pressure Cuff is an accessory used in conjunction with non-invasive blood pressure measuring devices to measure systolic and diastolic blood pressures and heart rate. It is non-sterile and may be used with neonatal, pediatric and adult patients. The cuff is not designed, sold or intended for use except as indicated:

Prescription Use, Part 21 CFR 801 Subpart D

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Performance Summary:
The Legacy Medical blood pressure cuff has been tested according to the following standards:

- ANSI/AAMI SP10, Manual, electronic or automated sphygmomanometers, 2002+A1:2003+A2:2006+(R)2008
- ISO 10993-5, Biological evaluation of medical devices, Part 5: Tests for In Vitro cytotoxicity, 1999
- ISO 10993-12, Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials

Performance Data:

Non-clinical tests – comparative bench testing was utilized to assess and prove similarity of function between the Legacy Medical Blood Pressure Cuff and the predicate devices. Tests showed that the functional and operational performance characteristics including compression, pressure control, leakage and both safety and operational parameters used when connected to inflation and measurement equipment were substantially equivalent.

Test conclusion – Non-clinical test results of the Legacy Medical Blood Pressure Cuff indicated substantial equivalence in the measured characteristics to the predicate devices.

Statement of Substantial Equivalence:

The Legacy Medical Blood Pressure Cuff is substantially equivalent in technology, function, operating parameters, and intended use to the blood pressure cuffs that are currently commercially available and in distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 17, 2013

Legacy Medical, Inc.
C/O Deb Robertson
9039 Horizon Dr
Shakopee, MN 55379 US

Re: K130942
Trade/Device Name: Legacy Medical Eco-Choice Disposable Blood Pressure Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Non-Invasive Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: August 30, 2013
Received: September 16, 2013

Dear Deb Robertson:

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 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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K130942
Device Name: Eco Choice Blood Pressure cuff
Indications For Use:

The Legacy Medical Eco Choice Blood Pressure cuff is an accessory used in conjunction with non-invasive blood pressure measuring devices to measure systolic and diastolic blood pressures and heart rate. It is non-sterile and may be used with neonatal, pediatric and adult patients. The cuff is not designed, sold or intended for use except as indicated.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)
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Digitally signed by
Owen P. Faris -S
Date: 2013.10.17
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