DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 17, 2015

Renew Group Pte Ltd.
% Janice Hogan
Regulatory Counsel
Hogan Lovells US, LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K152115
Trade/Device Name: Renew™ NCP-5 External Counterpulsation System
Regulation Number: 21 CFR 870.5225
Regulation Name: External Counter-Pulsating Device
Regulatory Class: Class II
Product Code: DRN
Dated: November 23, 2015
Received: November 24, 2015

Dear Janice Hogan:

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 Industry and Consumer Education 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 Industry and Consumer Education 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 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement on last page*

510(k) Number *(if known)*

K152115

Device Name

Renew™ NCP-5 External Counterpulsation System

Indications for Use *(Describe)*

The Renew NCP-5 External Counterpulsation System is intended for the treatment of chronic stable angina that is refractory to optimal anti-anginal medical therapy and without options for revascularization. In addition, it is intended for use in healthy patients to provide improvement in vasodilation, increased VO2, and increased blood flow. It is intended for use under the oversight of a healthcare professional.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

# 510(k) SUMMARY

## Renew™ NCP-5 External Counterpulsation System

### Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Jonathan Helfgott, Renew Group Pte Ltd.
7811 Montrose Rd.
Rockville, MD 20854
732 -754-2073
Date Prepared: December 15, 2015

### Name of Device

Renew™ NCP-5 External Counterpulsation System

### Common/ Classification Name

Device, Counter-pulsating, External, 21 CFR 870.5225, Class II
Product code: DRN

### Primary Predicate Device

ACS Model NCP-2 External Counterpulsation Device (K042413)

### Indications for Use

The Renew NCP-5 External Counterpulsation System is intended for the treatment of chronic stable angina that is refractory to optimal anti-anginal medical therapy and without options for revascularization. In addition, it is intended for use in healthy patients to provide improvement in vasodilation, increased VO2, and increased blood flow. It is intended for use under the oversight of a healthcare professional.

### Technological Characteristics

The Renew™ NCP-5 External Counterpulsation System (ECS) is comprised of the following major components, a switch panel, laptop PC computer, a foldable treatment bed, main unit, and a set of patient cuffs. The device is a microprocessor-controlled system that sequentially inflates then deflates three pairs of air cuffs, which compress vascular beds in the muscles of the calves, thighs, and buttocks in synchrony with the heart cycle to achieve the desired therapy.

### Performance Data

Cytotoxicity, irritation, and sensitization testing per ISO 10993 was performed to evaluate the biocompatibility of the patient contacting materials. Electrical safety and EMC compatibility testing per IEC 60601 was performed to ensure appropriate electrical performance. The

software and firmware used in the system was validated per FDA's guidance document. In all instances, the NCP-5 system functioned as intended. In addition, a literature review regarding the use of external counterpulsation in healthy patients was provided to support this additional indication.

**Substantial Equivalence**

The NCP-5 system has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. Thus, the NCP-5 system is substantially equivalent to the predicate device.

**Conclusions**

The NCP-5 system is substantially equivalent to the predicate NCP-2 device.