



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

APR 17 2012

Novitas Medical, LLC
c/o Mr. William J. Sammons
Intertek Testing Services NA, Inc.
2307 E. Aurora Road, Unit B7
Twinsburg, OH 44087

Re: K121001

Trade/Device Name: Compression System – Models CMP-001 and CMP-002
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeves
Regulatory Class: Class II
Product Code: JOW, ILO
Dated: March 30, 2012
Received: April 2, 2012

Dear Mr. Sammons:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/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 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4Indications for Use Statement

510(k) Number (if known):

Device Name: Compression System - Models: CMP-001 and CMP-002

Indications for Use: The Compression System is intended to function as an intermittent, sequential pneumatic compression device and each model provides the following specific therapeutic functions:

The CMP-001 (Compression Plus) is intended for:

- Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema, chronic lymphedema.
- Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains.
- Optional localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions
- Aids the blood flow back to the heart
- Treats and assists healing of cutaneous ulceration (wounds), reduce wound healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications

The CMP-002 (DVTmax) is intended for:

- Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema chronic lymphedema
- Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains
- Optional localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions
- Decrease the risk of deep venous thrombosis (DVT)
- Aids the blood flow back to the heart,
- Treats and assists healing of cutaneous ulceration (wounds), reduce wound healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications

