13. 510(k) Summary per 21 CFR 807.92

Date Prepared	May 10, 2013
Submitter Information	Wright Therapy Products 103-B International Drive Oakdale, PA 15071-3907 Telephone: 800-631-9535 Fax: 724-695-0406
Contact Person	Carol Wright, Chief Technology Officer
Proprietary name of Device	Wright Gradient 52 – Torso and Wright 51 – Torso
Common Name:	Pneumatic compression pump
Device Classification:	21 CFR 870.5800, Class II, Sleeve, Limb, Compressible Product Code JOW
Predicate Device	Wright 51 and 52 Sequential Compression System (K071040)

NOV 2 0 2013

Device Description:

The Wright Gradient 52 – Torso and Wright 51 – Torso consists of a pneumatic compression pump, a hose assembly, and associated inflatable appliances. It is typically used to compress upper and lower body extremities and portions of the torso.

The pump consists of an enclosure that contains a small air compressor, solenoid valves, printed circuit board including a programmable microprocessor, graphic display, and associated electronic circuits and pneumatic connections. Software controls the sequential opening and closing of the solenoid valves, which are connected to five (5) external pressure ports.

The appliance assembly is made of fabric and consists of one or two limb appliances (for an arm or a leg) and a torso appliance (for abdomen or chest area). Each limb appliance comprises four cells, with the dimensions of the appliance dependent upon the physician's order and the patient's limb measurements. There are two basic variations of the torso appliance: (1) a vest-like appliance for compression of the upper torso; and (2) a girdle-like appliance for compression of the lower torso. In each case the dimensions of the appliance dependent upon the physician's order and the patient's anatomical measurements.

In operation, the pump fills the inflatable appliance(s) with air to compress the prescribed limb(s) and torso area with the prescribed pressures in a preset therapy program. The therapy program is based on manual lymph drainage massage principles and intended to improve lymphatic and venous return circulation for the patient.

Intended Use

Wright Gradient 52 – Torso and Wright 51 – Torso is for treatment of lymphedema, venous insufficiencies, and other edematous conditions.

Summary of technological characteristics compared to the predicate devices

The Wright Gradient 52 – Torso and Wright 51 – Torso has the following similarities to the technological characteristics of the previously cleared predicate device: Wright 51 and 52 Sequential Compression System, K071040):

- Same intended use
- Same operating principle
- Same fundamental scientific technology
- Same pump design
- Same materials used
- Similar appliance design
- Similar compression sequence

The Wright Gradient 52 – Torso and Wright 51 – Torso has the following differences in technological characteristics of the previously cleared predicate device (Wright 51 and 52 Sequential Compression System, K071040):

- The maximum pressure on the torso cell has been reduced to 30 mmHg.
- The appliances have been changed to include torso appliances and 4-cell limb appliances.
- The inflation sequence has been revised.
- The software algorithm for inflation and deflation is revised to accurately control pressure during the variable therapy program and the unique geometry of the torso cells.

Summary of non-clinical testing submitted, referenced, or relied on in the 510(k)

The evaluation of the device consisted of risk analysis to confirm that the device is as safe as the predicate devices and bench tests to verify conformity to performance specifications. Bench performance testing consisted of measurements of the sequence sequences, timing, and pressure of therapy delivery along with verification of the functionality of the operator interface. Bench performance testing was performed to verify equivalent performance. All tests were verified to meet acceptance criteria.

Conclusion

Based on the above, we concluded that the Wright Gradient 52 – Torso and Wright 51 – Torso is substantially equivalent to the identified legally marketed predicate device, is safe and effective for its intended use, and performs as well as the predicate device.

End of section.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 20, 2013

Wright Therapy Products
Ms. Carol Wright
Chief Technology Officer
103-B International Drive
Oakdale, PA 15071-3907

Re: K131387
Trade/Device Name: Wright 51 – Torso
Wright Gradient 52 – Torso
Regulation Number: 21 CFR 870.5800
Regulation Name: Cardiovascular
Regulatory Class: Class II
Product Code: JOW
Dated: August 21, 2013
Received: August 23, 2013

Dear Ms. Wright:

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" (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 Zuckerman, MD
Director, Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

6. Indications for Use

510(k) Number (if known): K131387

Device Name: Wright Gradient 52 – Torso and Wright 51 – Torso

Indications For Use:

Wright Gradient 52 – Torso and Wright 51 – Torso are for treatment of lymphedema, venous insufficiencies, and other edematous conditions.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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