ARJOHUNTLEIGH
GETINGE GROUP

FEB 2 8 2014
K133119

510(K) Summary
Flowtron ACS800 Pump and Tri Pulse Garments

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Prepared:	2 January 2014
Contact:	David Moynham – Regulatory Affairs Engineer
Device Name:	Flowtron ACS800 Pump and Tri Pulse Garments
Common Name	Compressible Limb Sleeve

Classification

Class	Product Code	Classification Regulation
II	JOW	870.5800

Classification Name: Sleeve, Limb, Compressible

Predicate Devices: Flowtron Universal AC600 (K010744) cleared 26 Mar 2002, originally manufactured by Huntleigh Healthcare Ltd.

and

STS garments (K012008) cleared 21 Sept 2001 originally manufactured by Huntleigh Healthcare Ltd.

Huntleigh Healthcare was acquired by the ArjoHuntleigh AB group and all rights to properties and registrations assigned to Huntleigh Healthcare are now wholly owned by ArjoHuntleigh AB.

Indications for Use: To help prevent Deep Vein Thrombosis (DVT)

Description : The Flowtron ACS800 pump is a pneumatic pump that supplies compressed air to inflate compression garments that are attached to patient's limbs.

It is designed to work with the ArjoHuntleigh ranges of DVT calf/thigh compression garments, Foot compression garments and Tri Pulse calf/thigh compression garments.

The pump automatically senses the type of compression garment connected and adjusts the pressure/time cycle accordingly.

Each garment is compressed alternately, applying pressure to the patient's limb, to help prevent deep vein thrombosis.

Models:

Model REF	Device	Features
513003	Flowtron ACS800	AC powered pump
513003OR	Flowtron ACS800	AC powered pump with longer length connection tubes
TRP10, TRP20, TRP30, TRP40 & TRP60	Tri Pulse garments.	Sequential inflation providing active compression.

Substantial Equivalence:

Flowtron ACS800 pump is substantially equivalent to cleared device Flowtron Universal AC600 (K010744). The Flowtron ACS800 pump has the same compression pressure / time profiles for the DVT and Foot Garments.

The equivalence of the Tri Pulse garments is demonstrated using bench testing against the predicate STS garments (K012008).

Tri Pulse garments are substantially equivalent to cleared device STS garments (K012008) having similar sequential compression profiles using three-chamber garments.

Both devices are intended to be used together as a system.

Testing to demonstrate equivalence included

Testing conducted	Result
Full validation of pump software / hardware functionality, including - Garment detection - Therapy delivery	Passed
Performance testing garments – Pressure cyclic test. with Tri Pulse garments with Foot garments with DVT garments	Passed
Real Time – life testing – pump.	Confirms specification
Vibration testing – pump.	Passed
Electrical Testing to Standard IEC 60601-1: 2005. + CORR. 1 (2006) + CORR. 2 (2007)	Complies with Standard

EMC testing to Standard EN 60601-1-2, 2007	Complies with Standard
Tri Pulse garment biocompatibility testing to standardsISO10993-1, ISO10993-5 & ISO10993-10	Complies with Standards

Technologies Summary:

The Flowtron ACS800 pump contains an air compressor, air distribution valve and a microprocessor based control system, housed in a durable plastic casing.

The control system sets and monitors the air pressure cycle applied to the compression garments. It also monitors for faults caused by incorrect user set-up, compression garment failures and pump system problems.

Automatic compression garment recognition is achieved by sensing a specific value inductor. The value inductor is built into the compression garment hose connector.

Tri Pulse garments are constructed with a three-chamber bladder enclosed in a polyester garment, which is wrapped around the limb and secured with hook and eye tabs. When connected to the pump, the garment inflates through a single connecting tube to generate a sequential compression effect on the limb.

Conclusion:

The data detailed within submission including that drawn from the nonclinical tests demonstrate that the device is as safe and effective as the legally marketed predicate devices.

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

February 28, 2014

Arjohuntleigh Polska Sp z.o.o.
Mr. David Moynham
Senior Regulatory Affairs Engineer
ArjoHuntleigh AB
35 Portmanmoor Road
Cardiff, CF24 5HN UK

Re: K133119
Trade/Device Name: Flowtron ACS800 pump and Tri Pulse garments
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: January 22, 2014
Received: January 27, 2014

Dear Mr. Moynham:

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,

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

Enclosure

ARJOHUNTLEIGH
GETINGE GROUP

510(k) Number: K133119

Device Name: **Flowtron ACS800 and Tri Pulse garments.**

Indications for Use:

To help prevent Deep Vein Thrombosis (DVT)

Prescription Use		Over-The-Counter Use
YES	AND/OR	**NO**
(Part 21 CFR 801 Subpart D)		(Part 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)