March 2, 2018

Getinge (Suzhou) Co., Ltd.
% David Moynham
Regulatory Compliance Manager
ArjoHuntleigh AB
35 Portmanmoor Road
Cardiff, cf24 5hn Gb

Re: K172103
Trade/Device Name: Flowtron DVT5 Small Calf Garment
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: January 10, 2018
Received: January 19, 2018

Dear David 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -S

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

Indications For Use

510(k) Number: K172103

Device Name: **Flowtron DVT5 Small Calf Garment**

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)

510(k) Summary
Flowtron DVT5 Small Calf Garments

Name & Address:	Getinge (Suzhou) Co., Ltd. No. 158 Fangzhou Road Sip, Suzhou, Jiangsu, Suzhou Jiangsu, CHINA 215024
Telephone:	+(44) 29 2044 7084
Fax:	+(44) 29 2049 2520
Prepared:	01 December 2017
Contact:	David Moynham – Regulatory Compliance Manager
Device Name:	Flowtron DVT5 Small Calf Garment
Common Name	Sleeve, Limb, Compressible

Classification	Class	Product Code	Classification Regulation
	II	JOW	21 CFR 870.5800

Classification Name:	Sleeve, Limb, Compressible
Predicate Device:	K925717, DVT10(S) Limb Compression Sleeves Calf Garments
Indications for Use:	• To help prevent Deep Vein Thrombosis (DVT)

Description :

The Flowtron Small Calf Garment is a wraparound Calf garment comprising of a bladder and surrounding material intended to apply cyclic compression to calf to improve return venous blood flow to prevent and reduce the risk of Deep Vein Thrombosis (DVT).

The Flowtron Small Calf Garment is connected to an ArjoHuntleigh Flowtron pneumatic pump. The pump controls and generated the delivery of air to inflate and deflate the Calf Garment in a cyclic manner.

Flowtron Calf Garments are configured with a custom design connector that means that they are only compatible with ArjoHuntleigh Flowtron pneumatic pumps.

Models

Model REF	Device	Feature
DVT5	Flowtron Small Calf Garment Up to 36 cm (14")	Smaller Size

Substantial Equivalence:

The Flowtron DVT5 Small Calf Garment and the DVT10(S) Calf Garment included in the predicate device clearance are identical in materials, function and indications for use.

The only difference being the size of the Flowtron Calf Garment.

Full details of the verification and validation of the smaller calf garments have been included in the submission.

Testing to demonstrate equivalence included:

Testing conducted	Result
Performance testing of garments – Pressure cyclic test with Flowtron pneumatic pumps.	Passed
Evaluation of durability of garment fastening.	Passed
Evaluation at environmental extremes.	Passed
Evaluation of shelf life	Passed
Evaluation of shipping and distribution	Passed
Evaluation of biocompatibility	Passed

Technologies Summary:

DVT garments are compression sleeves intended to be wrapped around patient calf. They inflate and deflate in a cyclic manner when connected to a Flowtron pneumatic pump. The garments are passive devices and do not contain any technologies. The Flowtron pneumatic pump is the active part of the system but is outside the scope of this application. The subject garment DVT5 is non-sterile and the predicate device is sterile.

The differences in garments are the size aspect. The difference being the size from DVT10(S) (Sleeves are extended in width, so that are suitable to fit a patient's calf of up to 17 inches circumference) to that of DVT5 (Small garment designed to fit calf circumferences up to 14inches).

Conclusion:

The submission device and the predicate device are identical in in materials, function and indications for use.

The differences are the width and the height of the submission device.

The data detailed within submission including that drawn from the nonclinical tests demonstrate that the predicate and the submission device are substantially equivalent.