4/28/99

K983680

Section 2

510(k) Summary

Delphi Consulting Group
Stafford, Texas 77477

REGULATORY OFFICES
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Summary

The following is a Summary of the Trinity II Single Chamber DVT Pump 510(k) submission.

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Printed Name J. Harvey Knauss

Signature J. Harvey Knauss

Title Owner

Date Oct 16, 1998

CLASSIFICATION NAME:	Compressible Limb Sleeves
COMMON/USUAL NAME:	Extremity Sleeve and Pump
PROPRIETARY NAME:	Trinity II Single Chamber DVT Pump
CLASSIFICATION:	21 CFR Part 870.5800 Compressible Limb Sleeve, Class II
PERFORMANCE STANDARDS:	No Performance Standards for the Compressible Limb Sleeve are in effect.
PREDICATED DEVICE	Trinity II Single Chamber DVT Pump is the same as the Pump released to market under K881632, Huntleigh Technology, Inc. Flowtron DVT System AC500 Pump.

INDICATIONS

The Trinity II Single Chamber DVT Pump is designed to reduce pooling of blood, increase venous blood flow in the lower extremities of the recumbent patient to reduce deep vein thrombosis and pulmonary embolism. The intended patient population is adult with the environment of use being hospital or clinic.

CONTRAINDICATIONS

The Trinity II Single Chamber DVT Pump with sleeves should not be used during episodes of pulmonary embolism or in any instance where increased venous return or lymphatic return is undesirable. Do not use on a patient with burns, open wound, rash or fracture. Use with caution on extremities which are not sensitive to pain. Do not counter accepted clinical practice or institution guidelines.

TESTING

Electrical Safety tested to UL 2601.

EMI tested to IEC 801-2, –3, -4, -5, IEC 1000-4-11, and EN 61000-4-5, -4-11.

Alarm and Timing tested to Delphi Consulting Group protocol.

Y2K – software has been tested for any problems with year 2000 problem. Software does not retain dates.

Risk Analysis per EN 1441 and EN 46001.

SAFETY

Preponderance of problems associated with the use of a Compression Sleeve Systems is improper operation of the system not system failure.

Sleeve problems are:

1. Puncture or cuts that destroy the integrity of the air chambers.

2. Dry Cleaning, Steam or Dry Heat Sterilization that destroys the sleeves.

Operator Errors are:

1. Sleeve applied too loose.

2. Sleeve applied too tight.

SUBSTANTIAL EQUIVALENCE

The Trinity II Single Chamber DVT Pump is identical in every feature to the K881632, Huntleigh Technology, Inc. Flowtron DVT System AC500 Pump. The Sleeves are released to market via K954489, Trinity Sleeve(s).

Comparison of features and principles of operation between the Trinity II Single Chamber DVT Pump and predicate device in the market via Section 510(k) of the "Act."

Parameter	Trinity II DVT Pump	Huntleigh Technology Pump K881632
Pump pressure range	20 – 60 mm Hg.	30 – 60 mm Hg.
Default pressure	40 mm Hg.	40 mm Hg.
Cycle time Approx.	Inflation 12 seconds Deflation 48 seconds	Inflation 12 seconds Deflation 48 seconds
Indications	Trinity Single Chamber DVT Pump is designed to reduce pooling of blood, increase venous blood flow in the lower extremities of the recumbent patient to reduce deep vein thrombosis and pulmonary embolism.	Huntleigh Technology Flowtron Pump is designed to reduce pooling of blood, increase venous blood flow in the lower extremities of the recumbent patient to reduce deep vein thrombosis and pulmonary embolism.
CE Mark	No	Yes

CONCLUSIONS The conclusion drawn from the above is that the Trinity II Single Chamber DVT Pump is equivalent in safety and efficacy to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 1999

Mr. J. Harvey Knauss
Consultant
Delphi Consulting Group
11874 South Evelyn Circle
Houston, TX 77071

Re: K983680
Trinity II Single Chamber DVT System Pump
Regulatory Class: II (Two)
Product Code: 74 JOW
Dated: January 29, 1999
Received: February 1, 1999

Dear Mr. Knauss:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K983680

Device Name: Trinity II Single Chamber DVT System Pump

Indications for use: The Trinity II Single Chamber DVT System Pump (with sleeves), is designed to reduce pooling of blood, increase venous blood flow in the lower extremities of the recumbent patient to reduce deep vein thrombosis and pulmonary embolism. The intended patient population is adult with the environment of use being hospital, clinic.

Prescription Device: Federal Law (US) restricts this device to sale by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

/Steven D. Lumpkin/

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983630

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)