

75103451

NOV - 4 1997

**Section 2**  
**Summary & Certification**

The following is a Summary & Certification of the Trinity DVT System.

I certify that I have conducted a reasonable search of all information known or otherwise available to me about the types and causes of safety and/or effectiveness problems that have been reported for a Compressible Limb Sleeve.

Printed Name J. Harvey Knauss

Signature

J. Harvey Knauss

Title

Owner

Date

Sep. 30, 1996

Delphi Consulting Group, P. O. Box 932, Stafford, Texas 77477, 713-723-8169  
Fax 713-723-4080

---

<b>CLASSIFICATION NAME:</b>	Compressible Limb Sleeves
<b>COMMON/USUAL NAME:</b>	Extremity Sleeve and Pump
<b>PROPRIETARY NAME:</b>	Trinity DVT System Sleeves and Pump
<b>CLASSIFICATION:</b>	21 CFR Part 870.5800 Compressible Limb Sleeve, Class II
<b>PERFORMANCE STANDARDS:</b>	No Performance Standards for the Compressible Limb Sleeve are in effect.
<b>PREDICATED DEVICE</b>	Sleeves are the same as the sleeves released to market under <i>K954489, 27-SEP-95, Trinity Sleeve(s), Delphi Consulting Group</i> . The pump is substantial equivalent to the Huntleigh Technology, K910188.
<b>INDICATIONS</b>	The Trinity DVT System ( <u>sleeve</u> ) 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.

**CONTRAINDICATIONS**

The Trinity DVT System Sleeve and pump 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.

**SAFETY**

Preponderance of problems associated with the use of a Compression Sleeve system 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.

Pump problems are:

1. Wrong pressure settings.
2. Air hoses not connected property.
3. Any of the above listed problems.

**SUBSTANTIAL EQUIVALENCE**

The Trinity DVT System sleeve(s) are identical in every feature to the Trinity Sleeves released to market under K954489, 27-SEP-95, *Trinity Sleeve(s), Delphi Consulting Group*. The pump is substantial equivalence to the Huntleigh Technology, K910188.



NOV - 4 1997

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. J. Harvey Knauss  
Delphi Consulting Group  
P.O. Box 932  
Stafford, Texas 77497-0932

Re: K963957  
Trinity DVT System  
Regulatory Class: II (Two)  
Product Code: JOW  
Dated: August 12, 1997  
Received: August 13, 1997

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 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.

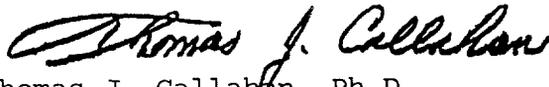
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. J. Harvey Knauss

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" (21 CFR 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/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

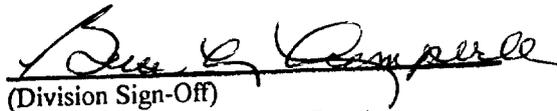
510(k) Number (if Known) K 96 39 57

Device Name: Trinity DV System, Compressible Limb Sleeve and Pump, Single Chamber

Indications for use: The Trinity DVT System 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K 96 39 57

Prescription Use  X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)