DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 1999

Mr. J. James Britton
President
Britt Corporation, Inc.
P.O. Box 547
Freehold, NJ 07728

Re: K974393
Vaso Press System
Regulatory Class: II (Two)
Product Code: 74 JOW
Dated: December 17, 1998
Received: December 21, 1998

Dear Mr. Britton:

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,

Thi,

Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K074319

Device Name:

vASO PRESS SYSTEM

Indications For Use: Treatment of lymphatic and venous disorders.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

cg /,

(Division Sign-Off)
rnvision oi' Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number bC\1-4'i>

Prescription Use J/ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 1999

Mr. J. James Britton
President
Britt Corporation, Inc.
P.O. Box 547
Freehold, NJ 07728

Re: K974393
Vaso Press System
Regulatory Class: II (Two)
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Sincerely yours,

T "

D irector

Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

51O(k) Number (if known):_K974393,________

Device Name:____VASOPRESS SYSTEM____

Indications For Use: Treatment of lymphatic and venous disorders.

(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 b cfi-4

Prescription Use J, OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Appendix J. 510(k) Statement

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Name: J. James Britton
Address: **Britt** Medical Products
PO Box 547
45 East Main Street, Suite 204
Freehold, NJ 07728

Contact Person: J. James Britton
Phone Number: (732) 863-1400
Fax Number: (732) 863-1603

This statement regarding 51O(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.93.

I certify that in my capacity as PRESIDENT OF BRITT MEDICAL PRODUCTS I will make available all information included in this premarket notification on safety and effectiveness within 30 days ofrequest by any person if the device described in the premarket notification is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Sign
Name: . "tton

Position: President

DEPARTMENT OF-HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Date:

From: Reviewer(s) - Name(s)

5 l O(k) Number_.:

Subject:

To: The Record - It is my recommendation that the subject 510(k) Notification:

dis substantially equivalent to marketed devices.

D Requires premarket approval. NOT substantially equivalent to marketed devices.

D Requires more data.

D Accepted for review_____

(date)

D Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	·DYES	rnt\fo
Ts this device subject to the Tracking Regulation?	DYES	o
as clinical data necessary to support the review of this 51O(k)?	DYES	rnNO
Is this a prescription device?	S	ONO

This 51O(k) contains:

Truthful and Accurate Statement DRequested 10'Enclosed
(required for originals receJYed 3-14-95 and after)

DA 510(k) summary OR r1A 510(k) statement

D The required certification and summary for class ID devices

The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under :2iCFR 807.95 (doesn't apply for SEs):

&No Confidentiality o Confidentiality for 90 days o Continued Confidentiality exceeding 90 days

Predicate ProdCode with panel and class:

Additional Product Code(s) with panel (optional):

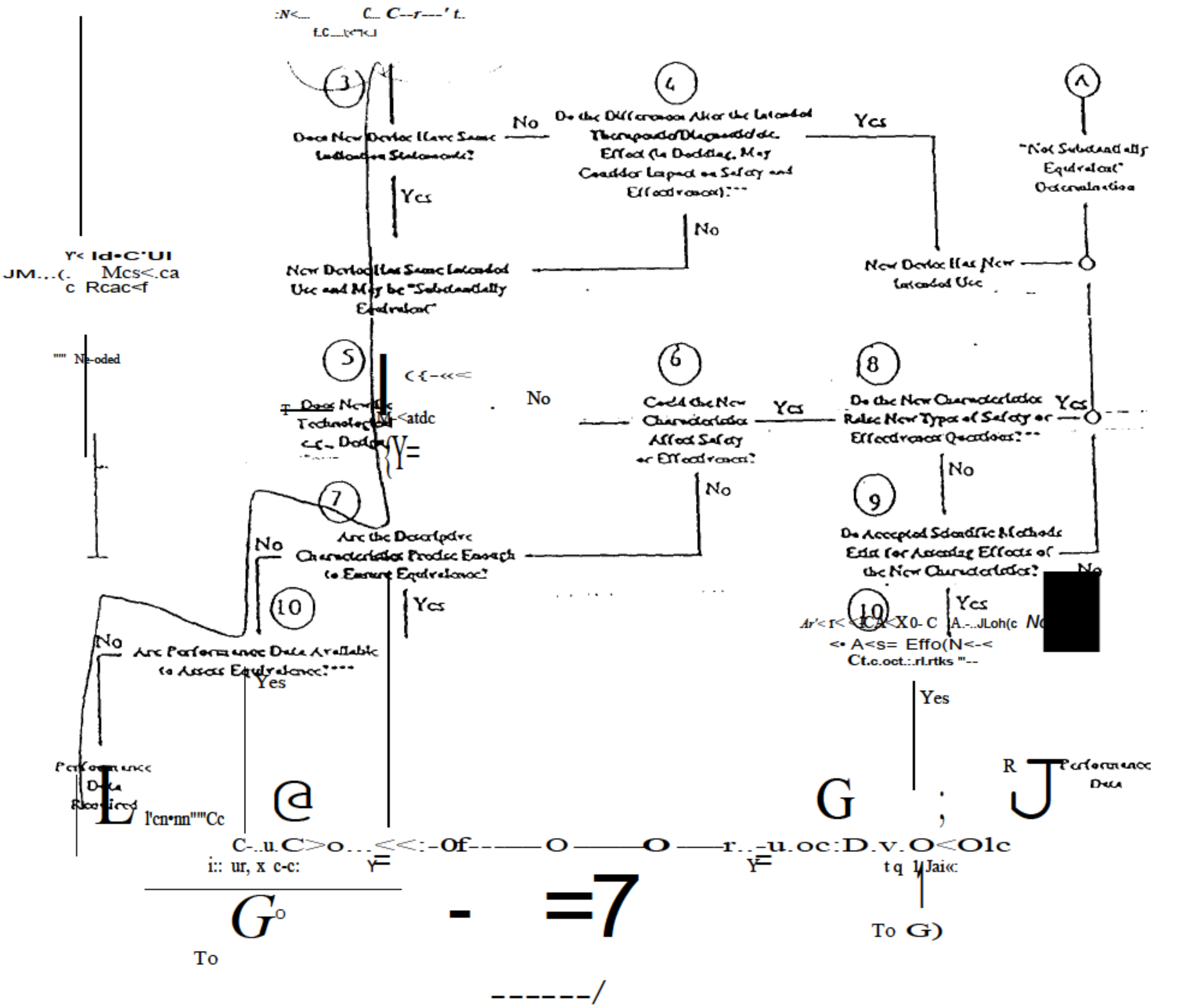
(BranhLhie!), (Cnranch O), r (Dtj

Final Review:

(Divisio Di rector) (Date)

Revised: 1-2-96

s lO(k) :su nSTANTlAL EQ U I VA LENCE"
O lClSION-MAKIN G PROCESS (O ETAI LEO)



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This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

510(k) Number (if known): K 974393

Device Name: VASO PRESS SYSTEM

Indications For Use: Treatment of lymphatic and venous disorders.

(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 K974393

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Office of Device Evaluation

MEMORANDUM

TXR 15 March 99

BC 16 Mar 99

Date: 3 February, 1999

From: Joydeb Roy
Physicist
DCRND/CSPG

To: File: K974393/S2

Sponsor: Britt Corp.

Subject: Additional Review

Action: Substantial Equivalence (SE)

SUMMARY OF FINDING:

The company has provided additional information dated December 17, 1998 in response to FDA's letter of August 26, 1998. The response addresses the issues raised in the FDA letter. The submitter has responded satisfactorily to the issues. Details are provided in the next page.

Based on the information provided and our review of that information, the submission is judged to be substantially equivalent to the predicate (s).

RESPONSE TO AUGUST 26, 1998 LETTER

QUESTION 1: With regard to electromagnetic compatibility (EMC) testing, please address the following concerns:

a. Section 4 of the test report indicated that conducted and radiated emission testing are not performed because the device does not contain "any component that is generating interference above the specified limits" in the frequency ranges 150 kHz to 30 MHz (conducted emission) and 30 MHz to 1 GHz (radiated emission). Please provide scientific justification for your claim or perform the appropriate test and provide the test results.

RESPONSE: (b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

FDA: The response is satisfactory.

b. Electrostatic discharge (ESD) testing was performed in accordance with IEC 60601-1-2 clause 36.202.1. This clause required ESD testing to be performed using the test method specified in IEC 801-2. A test severity level of 3kV contact discharge shall be applied to conductive accessible parts and coupling planes. In addition, IEC 801-2 requires the following:

(i) if a test severity level is selected, all lower levels must be satisfied;

(ii) discharges to the horizontal and vertical coupling planes should be performed; and

(iii) discharges shall be applied in the most sensitive polarity.

Therefore please address the following concerns:

i. Please clarify whether all lower levels were tested (+/- 2 and 4 kV for air discharge and +/- 2 kV for contact discharge). If the device was not subjected to these test levels, please perform the additional tests and provide the results.

(ii) Please perform indirect ESD testing or provide a rationale for not performing this test.

(iii) Please provide a rationale for only subjecting the device to positive discharge.

RESPONSE: (b)(4) Commercial Confidential Data / Trade Secret (b)(4) Commercial Confidential D (s) / Proprietary Data (b)(4) Commercial

FDA: The response is satisfactory.

QUESTION 2: In the original submission, you indicated that your device is substantially equivalent to the Flowtron HC, Model Number AC200HC and associated garments manufactured by Huntleigh Healthcare. This device was cleared for marketing via 510(k), K874688. An evaluation of this 510(k) reveals that the AC200HC is a single chamber intermittent compression pump and thus, the sleeves to be used with the pump are all single chamber device. In contrast with the AC200HC, your device can be used with either the single chamber sleeves (i.e., uniform) or the multi-chamber sleeves (i.e., segmental, and gradient). In order to find your device substantially equivalent to the predicate device(s), please provide one of the following:

a. remove any reference to the multi-chamber sleeves from your submission;

b. provide a predicate device that can be used with both single and multi-chamber sleeves and produces the same inflation/deflation waveforms as those generated by your device; or

c. provide additional predicate devices that have the same characteristics as your device when used with the multi-chamber sleeves.

RESPONSE: (b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

FDA: The response is satisfactory.

QUESTION 3: Your response to question 1, part c, in the Jetter dated February 18, 1998 is inadequate. You were asked to perform tests on sleeve of all types and sizes you intend to market. However, you have only provided test results showing the waveforms that can be generated when the pump is used with uniform, segmental, or gradiaent sleeves. For those sleeves that you request clearance for marketing, please provide test results demonstrating that each sleeve (VP 101, VP 102, VP 120, VP 201, VP 202, VP 220, VP 301, VP 302, VP 320) inflates/deflates as designed (i.e., generate the appropriate waveforms) or provide justification why these tests are not necessary.

RESPONSE: (b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

FDA: The response is satisfactory.

QUESTION 4: It appears that the proposed pump has only two outputs, one for each side. Without the description of the multi-chamber sleeves, it is difficult to comprehend how these sleeves are being inflated/deflated with the proposed pump. If applicable, please provide a detailed description of these sleeves and explain the mechanism for inflating and deflating the sleeves.

RESPONSE: (b)(4)

FDA: The response is satisfactory.

QUESTION 5: The promotional material for the VasoPress device contains the following phrase: "Promotes Increased Circulation by Stimulating Natural Muscle Contractions". The manufacturer of the predicate device, Huntleigh, was asked to remove this claim from their labeling prior to FDA clearance of the device. Therefore, please provide data to substantiate your claim or remove it from the device labeling.

RESPONSE: (b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

FDA: The response is satisfactory.

RECOMMENDATION: The responses to all questions are satisfactory. There are no more issues to be resolved. The device is judged to be substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Hail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 22, 1998

BRITT CORP., INC.
PO BOX 547
FREEHOLD, NJ 07728
ATTN: J. JAMES BRITTON

510(k) Number: K974393
Product: VASO PRESS SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

"SUBSTANTIAL EQUIVALENCE" DECISION MAKING DOCUMENTATION

REVIEWER: J. «9L

DIVISION/BRANCH fu _u flt[_

TRADE NAME: V&,tJ f Cp

COMMON NAME: CrFNf 'tie ,f/e.ev;

PRODUCT TO WHICH COMPARED (510(k) NUMBER IF KNOWN)

	YES	NO	
1. IS PRODUCT A DEVICE?			- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	V		- IF NO STOP
3. SAME INDICATION STATEMENT?	/		- IF YES GO TO 5
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			- IF YES STOP NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?	✓		- IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			- IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?		✓	- IF NO GO TO 10 - IF YES STOP
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			- IF YES STOP NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?			- IF NO STOP NE
10. PERFORMANCE DATA AVAILABLE?			- IF NO REQUEST DATA
11. DATA DEMONSTRATE EQUIVALENCE?			SE

NOTE: IN ADDITION TO COMPLETING PAGE ONE, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

NARRATIV E DEVICE DESCRIPTION

1- INTENDED USE: Treatment lymphatic and venous disorders

2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? ls the device for home use or prescription use? Does the device contain drug or biological product as a component? ls this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

SUMMARY: &4 1/c_ J/ru_ v &frdj/rJ/

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1C I . Jhe PP , r <<

Inflate and deflate to invest the Vad flow in the extremities.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. EXPLAIN WHY NOT A DEVICE:

2. EXPLAIN WHY NOT SUBJECT TO SIO(k) =

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION:

4. EXPLAIN WHY THERE IS OR IS NOT A NEY EFFECT OR SAFETY OR EFFECTIVENESS ISSUE:

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS:

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS =

7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH: Incomplete

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR \.THY THE QUESTIONS ARE NOT NEW: ---

9. EXPLAIN \.THY EXISTING SCIENTIFIC METHODS CAN NOT BE USED:

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED: Bench waveforms for the sleeves, EMC test data, labeling

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT:

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hQ lt=tci=-1 pJ_ r

ATTACH ADDITIONAL SUPPORTING INFORMATION

K974393/ 52

BRITTCORP

P.O. Box 547 Freehold, NJ 07728
Phone (732) 817-1122 Fax (732) 817-1123

December 17, 1998

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
200 Corporate Boulevard
Rockville, MD 20850

Re: K974393
Product: Vasa Pres SysterfP

Attn: Document Control Clerk
Re: Response to August 26, 1998 Letter

This is in response to the request dated August 26, 1998 for additional information on the subject device.

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

Should you have any questions regarding the submission of this additional data please do not hesitate to contact me at 732-817-1122.

Sincerely,

J. James Britton
President

CK - 61

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

(b)(4) Commercial Confidential Data / Trade

Ref No. (b)(4) Commercial Confidential Data / Trade

DATE: 11/11/1998

1. Applicant — Caremed Supply Inc.

   B1, No. 1L Pao Hon Rd., Hsin Tien, Taipei Hsien 231, Taiwan, R.O.C.

2. Manufacturer — (b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

3. Description of Device — PUMP
   A) Model — 8050
   B) Serial No. — /;\
   C) Test Item — (1) Conduction (2) Clamp (3) ESD
   D) Power Supply — AC 120V, 60Hz

4. Date of Measurement — (b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

5 Place of Measurement

6. Measurement Results — The results obtained from the measuring of the above mentioned device are as shown in the attached sheets.

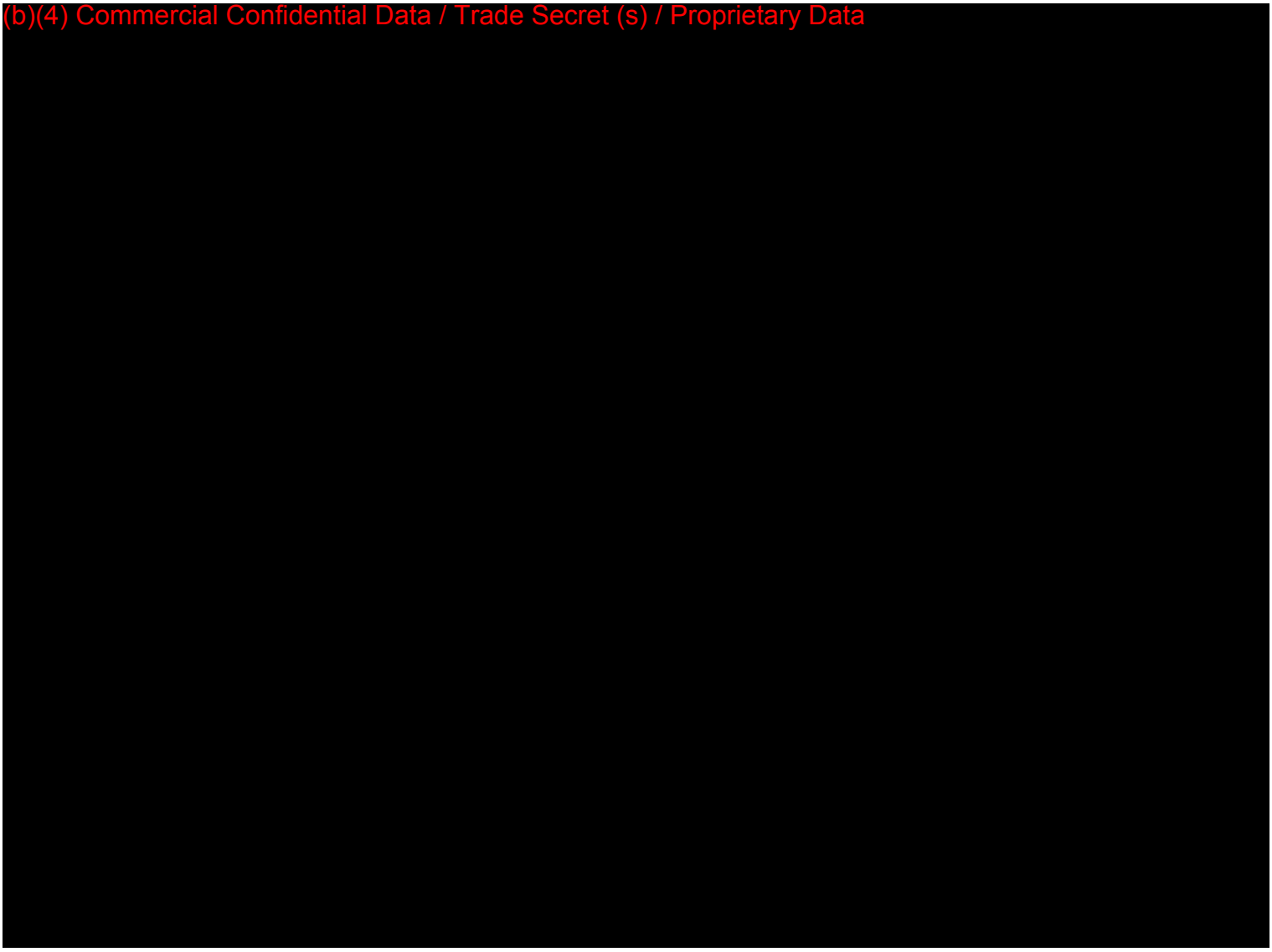
Allen Wang 11/16.1998

Allen Wang / Assistant Manager

1. Tested Instrumentation Used

1.1. For Conducted Measurement

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data



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2. Test Results

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

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(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

Electrostatic Discharge Measurement Results

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

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(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

November 03, 1998

BRITT CORP., INC.
PO BOX 547
FREEHOLD, NJ 07728
ATTN: J. JAMES BRITTON

510(k) Number: K974393
Product: VASO PRESS SYSTEM

Extended Until: (b)(4) Commercial Confidential Data / Trade Secret (s) /

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K974393

BRITT CORP

.0. Box 547 • 45 E. Main St. Suite 204 • Freehold, NJ 07728
Phone (908) 863 • 1400 Fax (908) 863 • 1603

October 28, 1998

CDRH
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: 51O(k) #K97439,_)

To Whom It May:

I am requesting a further extension to December 15 in order to comply with the request for additional information.

Thank you in advance for your assistance.

Sincerely yours,

J. James Britton
President

K-24

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Druq Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Hail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

September 25, 1998

BRITT CORP., INC.
PO BOX 547
FREEHOLD, NJ 07728
ATTN: J. JAMES BRITTON

510(k) Number: K974393
Product: VASO PRESS SYSTEM

Extended Until: (b)(4) Commercial Confidential Data / Trade Secret (s) /

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

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If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman...,
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Hail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

September 25, 1998

BRITT CORP., INC.
PO BOX 547
FREEHOLD, NJ 07728
ATTN: J. JAMES BRITTON

510(k) Number: K974393
Product: VASO PRESS SYSTEM

Extended Until: (b)(4) Commercial Confidential Data / Trade Secret (s) /

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

BRITT CORP

P.O. Box 547 • 11 IfAUI:: It ■ II 11l • Freehold, NJ 07728
'>hone (908) 863•1400 Fax (908) 863•1603

September 22, 1998

In reply to: 510(k) # K974393

CDRH
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

To Whom It May Concern:

We have recently received a request for additional information on our 51OK application and request additional time to comply.

It will take an additional 4 weeks to obtain the information and request an extension to November 1st in order to submit all the information

Thank you in advance for your cooperation

Sincerely yours,

J. James Britton
President

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Admi:iitration
9200 Corporate Boulevard
Rockville MD 20850

Mr. J. James Britton
President
Britt Corp., Inc.
45 East Main Street, Suite 204
Freehold, NJ 07728

AUG 26 \998

Re: K974393
Trade Name: Vaso Press System
Dated: May 28, 1998
Received: June 1, 1998

Dear Mr. Britton:

We have reviewed your Section SlO(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following:

1. With regard to electromagnetic compatibility testing, please address the following concerns:

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact Joydeb Roy at (301) 443-8262. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "dsmo@fdadr.cdrh.fda.gov".

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Prepared by:Jroy:jsy:B/25/98
cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

AUG 2 6 1998

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

U.S.GPO 1986-169-089

Mr. J. James Britton
President
Britt Corp., Inc.
45 East Main Street, Suite 204
Freehold, NJ 07728

Re: K974393
Trade Name: Vaso Press System
Dated: May 28, 1998
Received: June 1, 1998

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[redacted]

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

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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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Reviewer(s) - Name(s), [illegible] K6,t-

Subject: 510(k) Number K-.::-' _: 4L_:::!:...C-.L3-(S

To: The Record - It is my recommendation that the subject 510(k) Notification:

DRefused to accept.

equires additional information (other than refuse to accept).

DAccepted for review

Llis substantially equivalent to marketed devices.

DNOT substantially equivalent to marketed devices.

De Novo Classification Candidate? DYES D NO

DOther (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	DYES	l!f NO
Is this device subject to the Tracking Regulation?	DYES	NO
Was clinical data necessary to support the review of this 510(k)?	DYES	0NO
Is this a prescription device?	IBYES	O NO
Was this 510(k) reviewed by a Third Party?	DYES	IB'No
Special 51O(k)?	DYES	O NO
Abbreviated 51O(k)?	DYES	C!J NO

This 51O(k) contains:

Truthful and Accurate Statement rtRequested ra' Enclosed
(required for originals received 3-14-95 and after)

ifA 510(k) summary OR lifA 510(k) statement

D The required certification and summary for class III devices

c:9" The indication for use form (required for originals received 1-1-96 and after)

D Material of Biological Origin D YES r.0 NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

CCl No Confidentiality D Confidentiality for 90 days D Continued Confidentiality exceeding 90 days

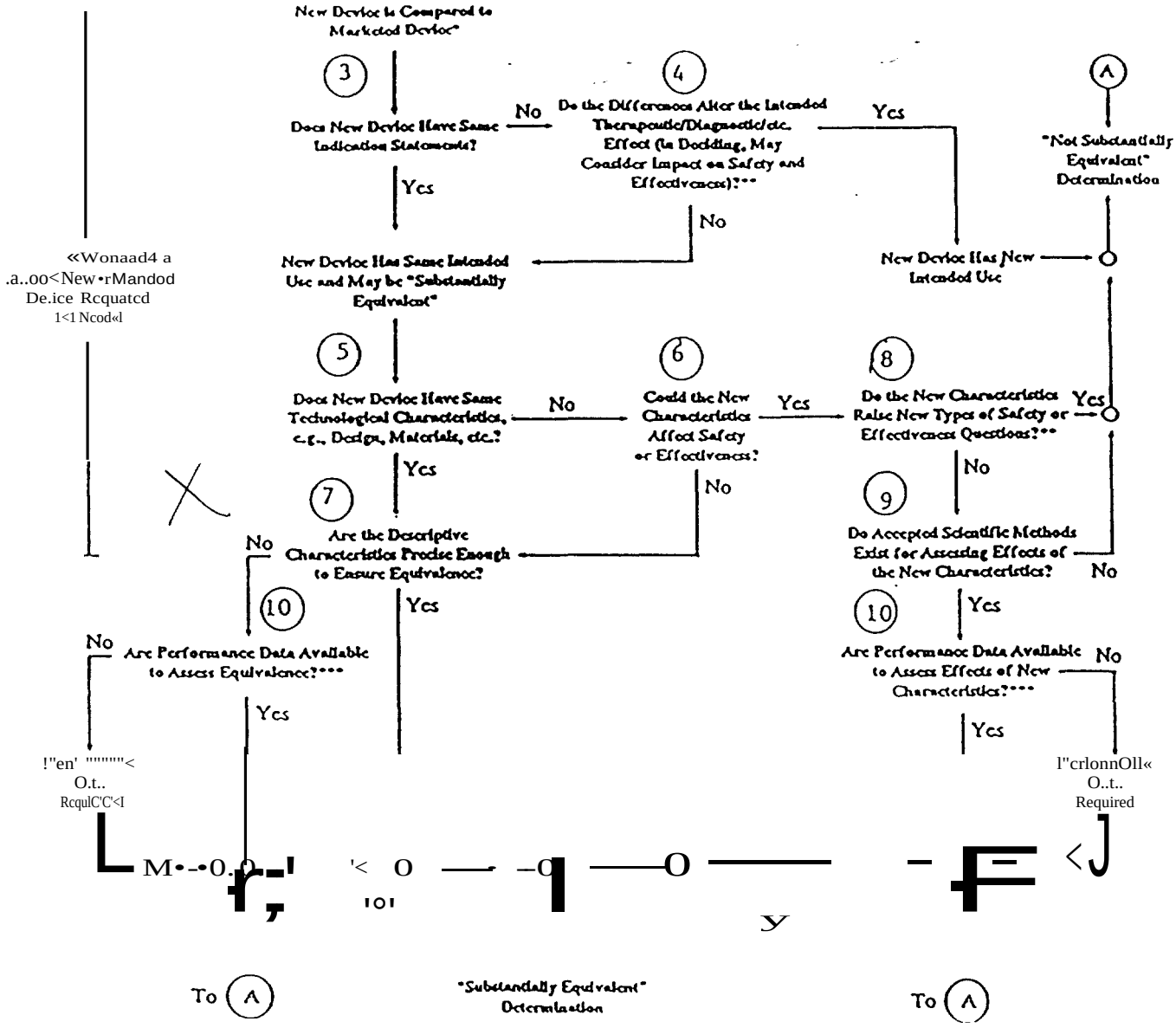
Predicate Product Code with class: Additional Product Code(s) with panel (optional):

Review: _____
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

(Date)

SlO(k)sunSTANTIAL EQUIVALEN CE·
DECISION-MAKING PROCESS (DETAILED)



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This decision u normally bas.cd on descriptive inf0<mation alone. but limited tc.s<ing infocmition u somc1imes required.

• - • O.it nu y lx: in I lic 5\0(lo:). 01l1cr 510(k)s, t he Center's **dufiotion fil.** or t he li1cr .itu rc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food! and Drng Administration
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Office of Device Evaluation

MEMORANDUM

Date: 24 August, 1998

From: Dr. Joydeb Roy
Physicist
DCRND/CSPG

To: File:K974393/Sl

Sponsor: Britt Corp.

Subject: **Additional** Review

Action: **Additional Information (AI)**

SUMMARY OF FINDING:

The company has provided additional information in response to FDA's letter of February 19, 1998. The response addresses many of the issues raised in the FDA letter. However, there are still some problem area, for example, electromagnetic compatibility testing, performance testing of sleeves, indications for use form and promotional material. The response is unsatisfactory. The details are discussed below.

The submission is judged deficient (AI). A letter is being prepared.

RESPONSE TO QUESTIONS

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food 1ndl Drug Adlmi nistiradon
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Office of Device Evaluation

MEMORANDUM

Date: 24 August, 1998

From: Dr. Joydeb Roy
Physicist
DCRND/CSPG

To: File:K974393/Sl

Sponsor: Britt Corp.

Subject: Additional Review

Action: Additional Information (Al)

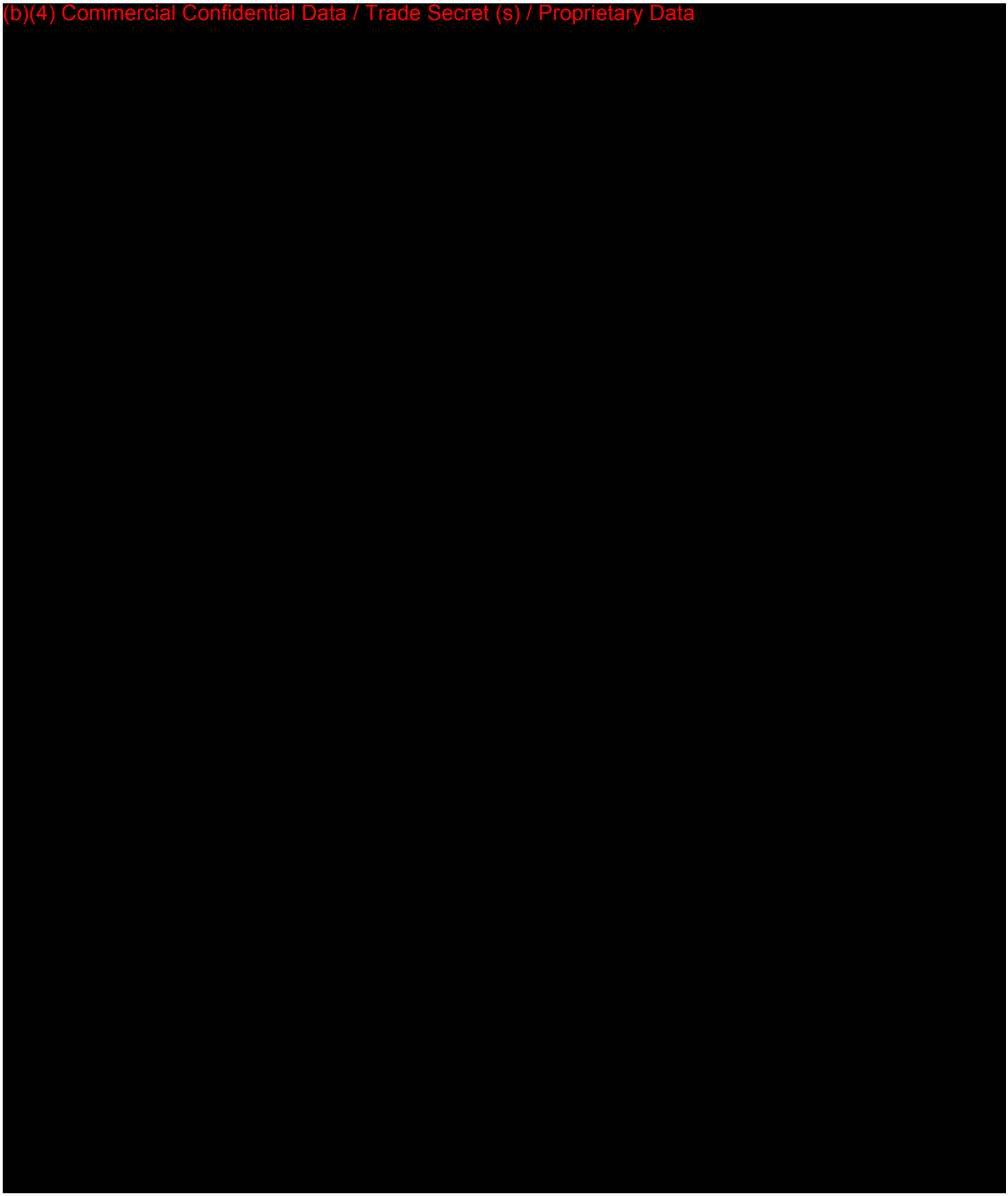
SUMMAR.¥ OF FINDING:

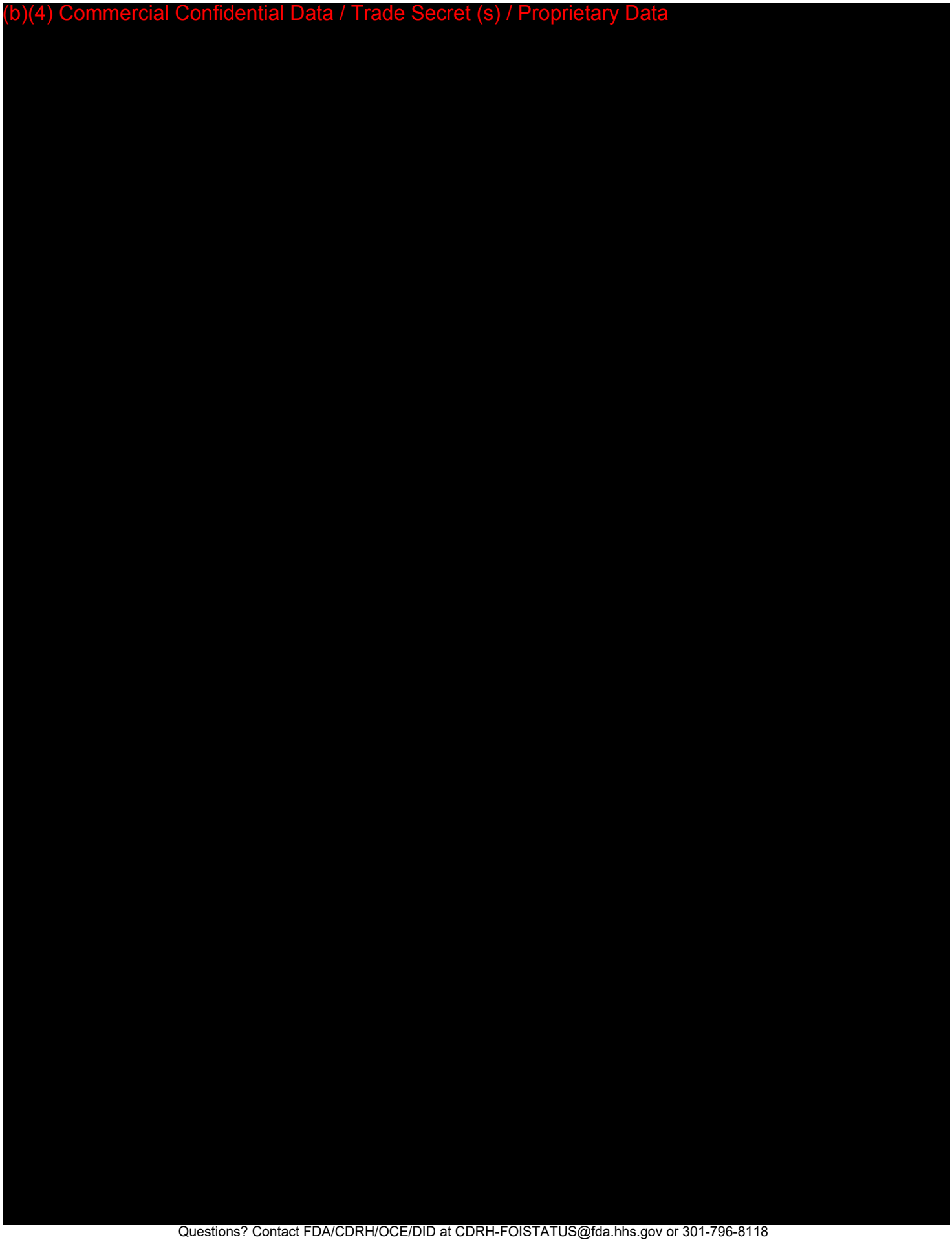
The company has provided additional information in response to FDA's letter of February 19, 1998. The response addresses many of the issues raised in the FDA letter. However, there are still some problem area, for example, electromagnetic compatibility testing, performance testing of sleeves, indications for use form and promotional material. The response is unsatisfactory. The details are discussed below.

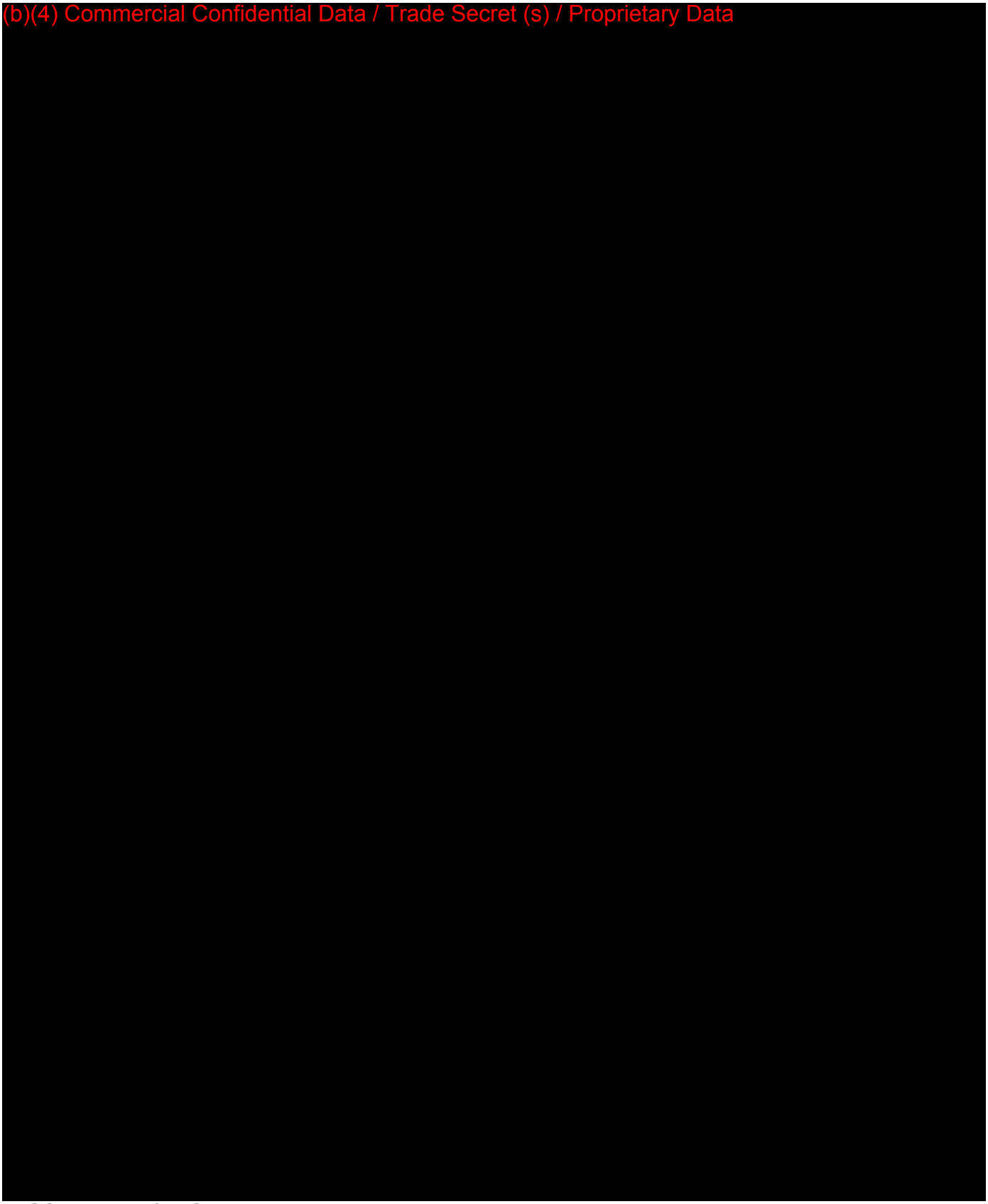
The submission is judged deficient (AI). A letter is being prepared.

RESPONSE TO QUESTIONS

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data







RECOMMENDATION: The response is still deficient. A letter is to be mailed for additional information.

K-3

CANNOT DETERMINE EQUIVALENCY LETTER - NEED MORE INFORMATION

Mr. J. James Britton
President
Britt Corp., Inc.
45 East Main St., Suite 204
Freehold, NJ 07728

Re: K974393/S 1
Trade Name: Vaso Press System
Dated: June 1, 1998
Received: June 5, 1998

Dear Mr. Britton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following:

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device forinvestigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 51O(k); therefore, all information previously submitted must be resubmitted so that your new 51O(k) is complete.

The requested information, or a request for an extension of time, should reference your above 51O(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health

Document Mail Center (HFZ.401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact [DIVISION REPRESENTATIVE] at (301) 594-[ ]. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 63g2041 or at (301) 443-6597, or at its internet address "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,

[Division Director]

Office of Device Evaluation
Center for Devices and
Radiological Health

cc: HFZ-401 DMC
HFZ-404 51O(k) Staff
HFZ- Division
D.O.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

June 02, 1998

BRITT CORP., INC.
45 EAST MAIN ST., SUITE 204
FREEHOLD, NJ 07728
ATTN: J. JAMES BRITTON

510(k) Number: K974393
Product: VASO PRESS SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

69

K974393/S1

BRITT CORP

P.O. Box 547 • 45 E. Main St. Suite 204 • Freehold, NJ 07728
Phone (908) 863 • 1400 Fax (908) 863 • 1603

May 28, 1998

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
200 Corporate Boulevard
Rockville, MD 20850""

Re: K974393
Product: Vaso Press System

This is in response to the request dated February 19, 1998 for additional information on the subject device.

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

I trust this additional information is helpful in making you assessment regarding the substantial equivalency of this device. If you have any questions regarding this application or contents please feel free to contact me at 732-817-1122.

Sincerely,

J. James Britton
President

APPENDECES

Test Report No:

about

Electromagnetic Compatibility

Applicant:

Kind of Equipment: Pump

Type Designation: 7000, 8030, 8050, 9000

Standard: EN 60 601-1-2:1993 EN 61 000-3-2:1995
EN 61 000-3-3:1995

Date of Receipt of Test Item: 05.03.1998

Date of Testing: March 10/13, 1998

Test result: The above mentioned product has been tested and passed.

Der Sachverstandige: ilberprilft:
reviewed by

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

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Appendix D

Photographs of Test Sample

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

90

TÜV Rheinland
Product Safety GmbH
P 9 8 6 3 5 7 9

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

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TÜV Rheinland
Product Safety GmbH

CARE SUPPLY AMERICA, INC.
P.O. Box 66007, 2170 South 7th Drive
West Des Moines IA 50265 USA
Phone: (515) 285-4044 Fax: (515) 256-8197

May 22, 1998

Mr. Jim Britton
Britt Corporation
P.O. Box 547
Freehold, NJ 07728

Dear Jim,

This letter is in response to your request for clarification on the UL and CSA status of your model VP100 Vase Press.

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

Respectfully yours,

Tim McCarty
cc: file

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

CARE SUPPLY AMERICA INC
MR T MCCARTY
2170 S 7TH DR
PO BOX 66007
WEST DES MOINES IA 502135

Your most. rc:<:cnt list.Ing i8 shown below. Please review this information and nport. any inaccuracies to the UL Bngineermg sta±i rnerntwr who handled your UL proJ (X:t.

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

For information on placing an order for UL ListJng Cards in a 3 x [1 inch card format, please refer t.o the enclosed ordering informaLion.

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

r/\\

GARMENT COM_PARISON TABLE

PROD UCT TYID	(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data
Unifonn Compression	
Segmental Compression	
Gradient Segmental	

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INFLATION BURST TESTING

(b)(4) Commercial C fid ti l

FINAL REPORT: (b)(4) Commercial Confidential Data /

PRIMARY SKIN IRRITATION - ISO

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

MANAGEMENT OF THE STCD

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

Sponsor
Britt Curporat iu11
45 E. Main Street
Suite 204
P.O. Box 547
Freehold. NJ 0772

TABLE OF CONTENTS

STUDY SUMMARY

QUALITY ASSURA!\ICE STATEMENT

This study was conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of Toxikon Corporation, exempt from this Good Laboratory Practice Statement. included characterization and stability of the test article and its mixture with carriers, 21 CFR, Parts 58.l05 and 58.113.

The Quality Assurance Unit conducted inspections on the tollovving elates. The findings were reported to the Study Director and to Toxikun's :\/1anagernent.

INSPECTIONS	DATE OF INSPECTION	DATE REVIEWED MANAGEMENT	DATE REPORTED STUDY DIRECTOR
CLINICAL OBSERVATIONS	(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data		
RAW DATA			
FINAL REPORT			

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L//1LJ/f6
Date

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(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

510(k) Number (if known): K192413

Device Name: VASOPRESSYSTEM

Indications For Use: Treatment of lymphatic and venous disorders.

(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, Neurological and Ophthalmic Device

510(k) Number

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Hail Center (BFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 23, 1998

BRITT CORP., INC.
45 EAST MAIN ST., SUITE 204
FREEHOLD, NJ 07728
ATTN: J. JAMES BRITTON

510(k) Number: K974393
Product: VASO PRESS SYSTEM

Extended Until (b)(4) Commercial Confidential Data / Trade

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

 (974391)

BRITT CORP

P.O. Box 547 • 45 E. Main St. Suite 204 • Freehold, NJ 07728
t,one (908) 863 • 1400 Fax (908) 863 • 1603

March 19, 1998

Re: K9
o Press System

Center for Devices and Radiological Health
HFZ-401
Document Mail Center
9200 Corporate Boulevard
Rockville, MD 20850

Dear Sir or Madam:

We recently received a request for additional information regarding the above 51OK application.

It will take approximately 6 weeks to gather the required information and I respectfully request an extension to June 1st in order to submit all the information.

Thank you in advance for you consideration.

Sincerely,

J. James Britton
President

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administratior.
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1998

Mr ..J. James Britton
President
Britt Corp. Inc.
45 East Main Street, Suite 204
Freehold, NJ 07728

Re: K974393
Vaso Press System
Dated: November 18, 1997
Received: November 21, 1997

Dear Mr. Britton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following:

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigat_ional _purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations cf this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information

previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact Joydeb Roy, Ph.D., at (301) 443-8262. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,

. Thoma--J.- Callahan, P. .
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Page s - Mr. J. James Britton

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-450 Division
D.0.

Prepared by:JROY:erj:2/12/98:FINAL

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
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U.S. GPO 1986-169-089

103

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President
Britt Corp. Inc.
45 East Main Street, Suite 204
Freehold, NJ 07728

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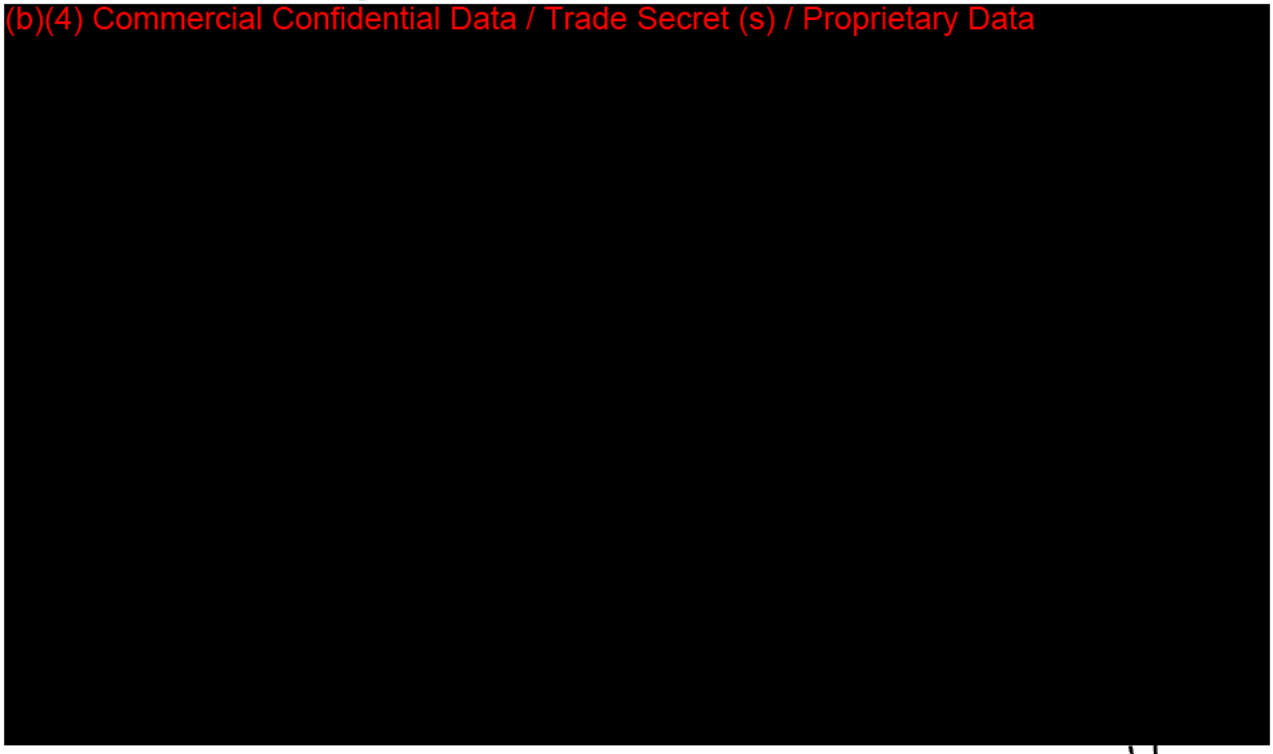
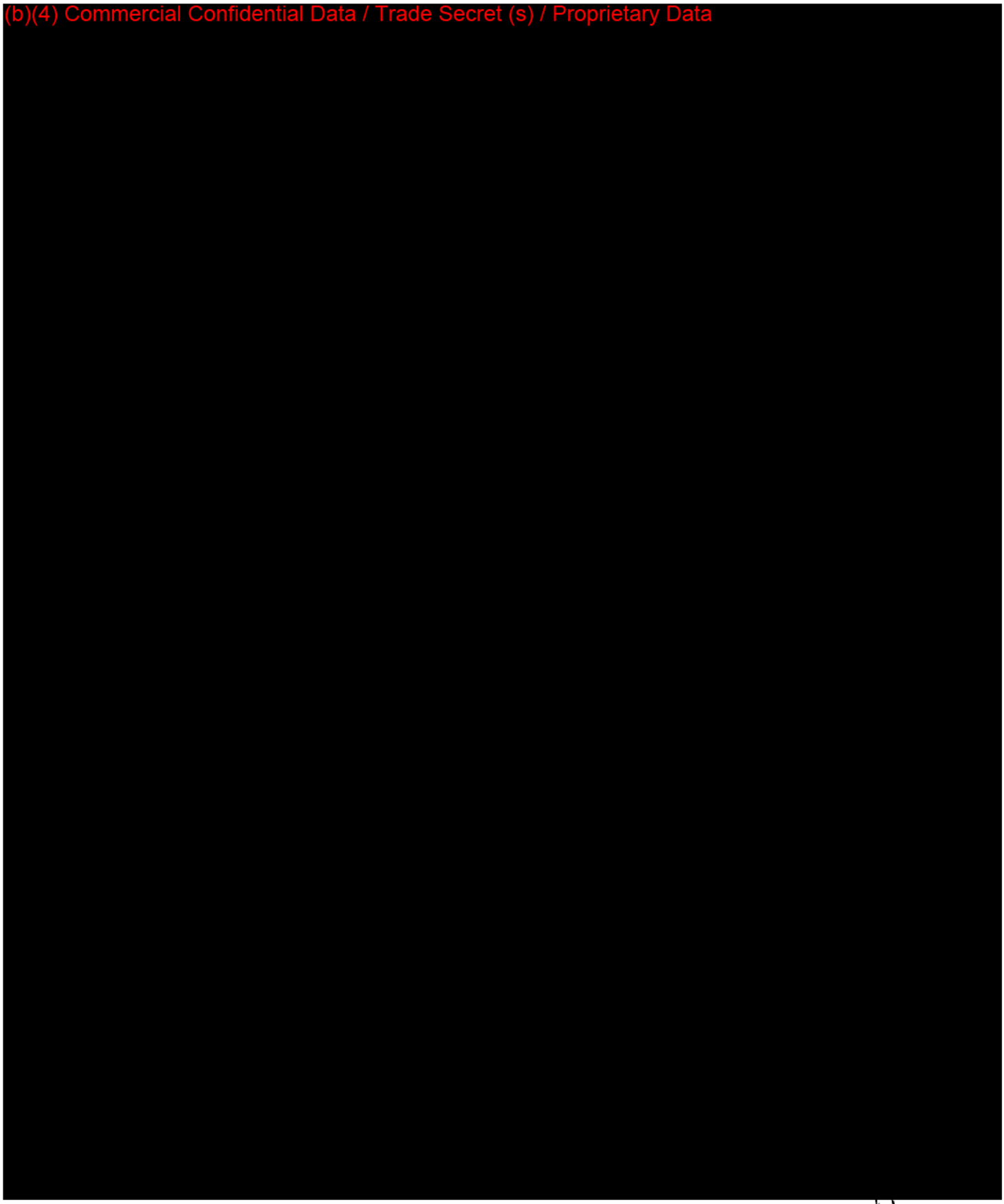
1. Please demonstrate that your device operates safely and effectively in its intended use environment by providing the following information:

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data



(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data



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[redacted]

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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

DEP.ART_MENT OF HEALTH & HUMAN SERVICES---_.. .-PUblic-Healtlf Serv ce -·------'
Food And Drug Administration

Memorandum

From: Reviewcr(s) - Name(s) _~tjljj}(/j<f_.

Subject: 510(k) Number , · -) r µ{-e/b ;2,/•:;

To: -'ihe.Record - It is my recommendation that the·subject5lO(k)·Notifrcatioh:-·

DRefused to accept. of7

tB'ilequires additional information (other than refuse to accept).

DAccepted for review_____

Dis substantially equivalent to marketed devices.

DNOT substantially equivalentto marketed devices.

Dother (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	DYES	li2f NO
Is this device subject to the Tracking Regulation?	DYES	fil NO
Was clinical data necessary to support the review of this 5lO(k)?	DYES	l2fNO
his a prescription device?	G1YES	O NO
was this 51O(k) reviewed by a Third Party?	DYES	*(!'.(NO*

This 51O(k) contains:

Truthful and Accurate Statement DRequested IBEnclosed
(required for originals received 3-14-95 and after)

El'A 510(k) summary OR DA 510(k) statement

D The required certification and summary for class III devices

D The indication for use form (required for originals received 1-1-96 and after) /Y"

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicat Product Code with class and tie;:: Additional Pro<luct Code(s) with panel (optional):

_____ _____

JOW II

(Branch Code) (Date)

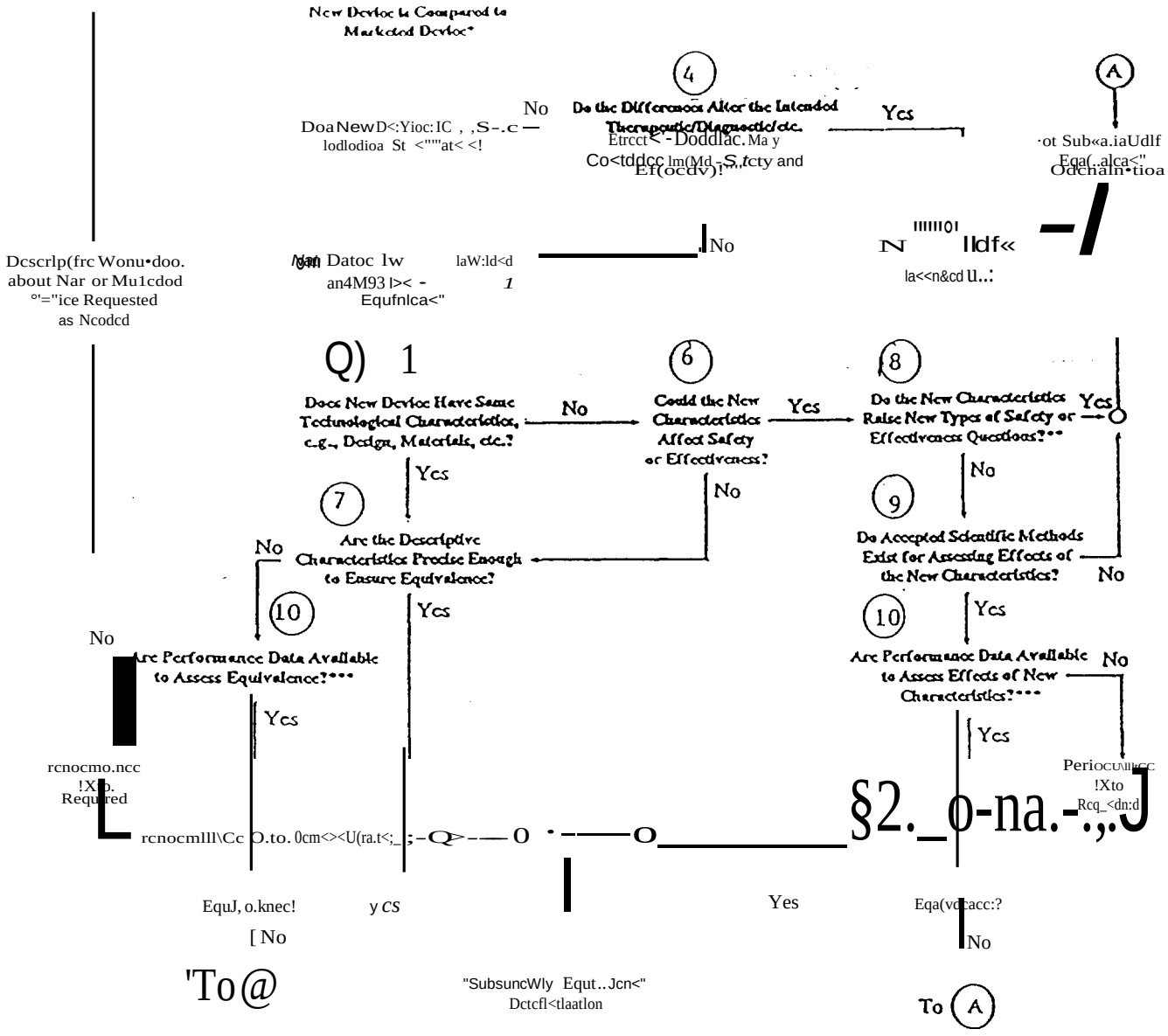
Review:_____

Review:_____ _____
(Branch Chief)

(Division Director) (Date)

108

SlO{k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



'iI.O{k) submissions <"Ornparc new dcvi;:.cs ro narkc:cd <levi=.. FDA <"c<iUCSlS additional informatiQa if lh,S: c-clat!9hlp b-..twi'. mac-kctc<l and "prcdic.ar_c.' (prc-Acucadmer.ts er rcd ificJ post-A.'"ltc1.dme. t>) dc..-iccs is undeai.

This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

••• Data may be in the 5lO(k), ocher SlO(k)s, the Ccnccc's classification files. or chc (i(cra.curc.

FOOD AND DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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DIVISION OF CARDIOVASCULAR AND RESPIRATORY DEVICES

CIRCULATORY SUPPORT AND PROSTHETICS GROUP

DEVICE REVIEW MEMORANDUM

Date of Review:	February 6, 1998
From:	Dr. Joydeb Roy (ODE/DCRND/CSPG)
To:	To the Record
Date Due:	February 19, 1998
Date Received in CSPG:	November 24, 1998
Submission Number:	K974393
Name of Device:	Vaso Press System, VP 100 and Sleeves
Predicate Device:	Flowtron HC (Huntleigh Technology)
Predicate 51O(K)#:	K874689
Name of Sponsor:	Britt Corp., Inc.
Name of Manufacturer:	Cathay Consolidated, Inc.
Type of Submission:	New
Contact:	J. James Britton (732-863-1400)
Code Class/CFR#:	JOW 11/870;5800
Consulting Reviews:	
Decision Status:	AI

BQ 19 Feb 98

ORIGINAL REVIEW

SUMMARY:

This is a compressible pump with sleeve(s) device. Following deficiencies have been noted with this submission:

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

A deficiency letter is being prepared and the device will be on hold pending satisfactory resolution of the issues raised.

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REVIEW ELEMENTS

1. **ADMINISTRATIVE**

a.	*Truthful and Accurate Statement:*	-/ *Yes*	*No*	
b.	*Indications for Use Form:*	*Yes*	V *No*	_ *Inadequate*
c.	*SIOK SE Statement*	-/ *Yes*	*No*	
d.	*Class III Certification*	*Yes*	_ *No*	V *NA*
e.	*Other*			

Indications for use form will he necessary

2. REASON FOR SUBMISSION

a.	*New device*	*!Yes*	*No*
b.	*Change(design/labeling/functionality)*	*Yes*	*No*
c.	*New Indication*	*Yes*	*No*
d.	*Shelf Life*	*Yes*	_ *No*
e.	*Sterilization*	*Yes*	_ *No*
f.	*Other*	*Yes*	_ *No*

No additional information necessary

3. INDICATIONS FOR USE

a.	*List of indications (Y)*	*b.*	*List of new indications*
c.	*Predicate indications comparison(N)*	*d.*	*Supportive data for new*
e.	*Clinical utility*	/.	*Documentation*
g.	*Environment of use(Y)*	*h.*	*Target population(Y)*
i.	*Indications for useform (N)*		

Statement oflntended Use under General Information Section states that the device is used in the treatment and management of venous and lymphatic disorders. Either a single or three chamber device is available. The three chamber sleeves provide either a segmental uniform pressure or a gradient pressure. The indication is language consistent with the predicate device.

However, promotional material information claims (Appendix D) that" Britt Medical Products Now offers a unique System that will maximize inventory investment and offer flexibility for your patients suffering from Jymphedema or venous ulcers". Ulcers were not included in the initial Statement of Intended use. Further, Appendix D lists also the suggested use as " Treatment of chronic venous insufficiency, including venous ulcers and edema, Lymphedema, primary and secondary". It is not clear what they mean by Lymphedema, primary and secondary. The intended use languages are not consistent with each other.

NOTE: It is not clear what is the "Unique Investment" they are talking about?
NOTE: Intended use languages are not consistent with each other..
NOTE: Indications for use form not provided . .

Additional information/clarification is necessary.

4. DESCRIPTION/PRINCIPLE OF OPERATION

a.	*Device description with components(N)*	*b.*	*Mode of operation(Y)*
c.	*Design goalslvalidation(N)*	*d.*	*Block diagram(N)*
e.	*Engineering/ circuit diagram(N)*	*f.*	*Photographs(Y)*
g.	*Operation manual(Y)*	*h.*	*Performance specification(Y)*
i.	*Material specification(Y)*	*j.*	*Safety features/alarms*
k.	*Characteristics (i.e., new technology, new material, new functionality) (N)*		

179

1. Lists of tests performed (Y,) *m. Other*

The air controller (pump) is a small and compact pump that provides an air source to inflatable limb sleeves. The sleeves are placed on the extremity and secured by a zipper closure so that the pressure derived from the controller is distributed over the extremity. One the sleeves are positioned they are attached to the controller by a connecting hose. The pump is then turned on and the pre-selected pressure is delivered to the extremity by the air pressure in the sleeve(s).

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

The following labeling information provided:
Preliminary labeling, labeling for the controller, labeling for the shipping cartoon, labeling for the sleeves.
Device operating instructions provided.

The labeling does not include the following statement, "Federal (USA) law restricts the devrc;to sale by or on the order of a physician or other licensed practioner.". traiudi'!'i!lQsyitement iycludeg in lb_e labelin_g_:: -
However, caution statement is included in the Instructions for use. nformation on treatment protocol provided.
Appendix D also lists preliminary catalog sheet. Instructions on device cleaning.

Labeling/promotional material/instructions for use for the Flowtron HC predicate device (AC200/2) provided, but not for the Jobst device. Huntleigh Flowtron HC pump is indicated for reduction in lymphatic, venous, and traumatic edema in the extremities by enhancing natural blood and lymphatic fluid flow. No mention of venous ulcer in the predicate.

NOTE: Jobst labeling information not provided.
NOTE: The indications for use need to be clarified.

The labeling information is inadequate and incomplete.

Additional information will be required.

6. COMPARISON WITH PREDICATE DEVICES:

a. Similarities/ Differences (design,functionality, per/ormance, sterility, shelf life,biocompatibility)

b.	Intended use (Y)		
c.	Performance	d.	Laboratory/bench testing (NJ
e.	Biocompatibility (NJ	f.	Clinical study(NA)
g.	Labeling	h.	System and material specification (NJ
L	Anatomical sites (1')	).	Animal testing(NA)
k.	Areas of concern/disagreement		

The listed predicate devices are Flowtron HC (K874688), and Jobst Extremity Pump Home Model 7000 (5 IOK #?). A comparison table is provided to compare the device with the Huntleigh Flowtron pump device but not the Jobst device. The features compared are Labeling, intended use, physical characteristics, anatomical sites, target population and safety characteristics. However, no performance comparison/data provided, no sleeve(s) comparison information provided.

NOTE: Jobst Extremity Pump Model 7000 is listed as one of the predicate device, but not included in the table of comparison. No 5 IO(k) of the predicate device supplied.

NOTE: UL certification for safety testing is pending. It is clarified what testing is done. 7
NOTE: No comparison of sleeves or performance data. The current table of comparison is incomplete.

Additional information will be necessary.

7. SOFTWARE

a.	Requirements	b.	Level of concern
c.	Hazard analysis	d.	Functionality testing
e.	Validation/verification	f.	Tests reports
g.	Certification	h.	Reference

NIA

8. ENVIRONMENTAL TESTING:

a.	EMC (N)	b.	Electrical safety(N)
c.	Temperature	d.	Pressure(Y)
e.	Component Failure	f.	Vibration, shock, drop (NJ
g.	Other		

In the table of comparison the submitter states that the UL Certification is pending, but does not state for what tests. Electrical safety testing/certification, electromagnetic compatibility (EMC) data/certification are required for the pump. An UL certification is attached, but we could not make out what it is for. So a clarification will be required.

NOTE: A copy of an article on Lymphedema Pumps: Pneumatic Compression Devices provided.
NOTE: No EMC testing, no sg ed.

Additional information will be required.

9. PERFORMANCE/FUNCTIONALITY TESTING

a.	Performance tests (Lists all functionality, performance tests performed) (Y)		
b.	Test objective/description (Y)	c.	Test protocol(Y)
d.	Pass\fail criteria (NJ	e.	Data plots (Y)
f.	Data accuracy & acceptability(N)	g.	Data analysis(N)
h.	Results/summary (N)	i.	Predicate device testing(N)
j.	Chemical tests (Hemolysis, thromboembolism, platelets, red blood cells, etc.)(NA)		
k.	Other tests		

Pressure (inflation/deflation pressures) testing data plots provided in Appendix F. A protocol for the pressure measurement provided to demonstrate that the system delivers the pressure to the extremity. Graphical data plots of cycle time (inflation and deflation times) in seconds against pressures in mm Hg are plotted. Three plots are included, one for uniform compression (single sleeve), one for segmental compression, and one for segmental gradient (distal, central and proximal) pressure.

No performance comparison with the predicate device provided, No data or measurement liccuracy provided. No EMC test data provided. No pass/fail criteria listed. No data table provided. Dafa generated for all the sleeve types and sizes are required. Further,, burst pressure data not provided.

Testing information is incomplete and inadequate.
Additional information will be required.

10. CLINICAL STUDY

a.	*General and specific objectives/hypotheses*		
b.	*End points/Outcome parameters*	*c.*	*Protocol*
d.	*Inclusion/Exclusion criteria*	*e.*	*Randomization*
f.	*ControVstudy groups*	*g.*	*Follow ups/monitoring*
h.	*Risk/benefit analysis*	*i.*	*Results/analysis*
j.	*Conclusions*	*k.*	*Bibliography*

NIA

11. ANIMAL TESTING

a.	*Objectives*	*b.*	*Protocol*
c.	*Results/conclusion*	*d.*	*Other*

NIA

12. BIOCOMPATIBILITY TESTING

a.	*List of component material(Y)*	*b.*	*List of patient -contacting material*
c.	*Final sterilized and aged product testing*		
d.	*Testprotocol (N)*	*e.*	*Pass/fail criteria(N)*
f.	*Testresults/data (N)*	*g.*	*Toxicology profile*
Ir.	*Certification(N)*	*i.*	*Reference standards*
j.	*Other*		

The submitter states that the sleeve material does not come in contact with the patients skin, therefore no biocompatibility assessments are provided.

The material does contact patients and hence biocompatibility information or reference to documentation about their biocompatibility are required. Material specification information also required.

Additional information will be required.

13. STERILITY TESTING

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

The device is non-sterile, but the predicate is sterilizable. Cleaning information provided.

The information is adequate.

No additional information is necessary.

14. PACKAGING & SHELF LIFE

a.	*Packaging method*	*b.*	*Shelf life testing*
c.	*Testing performed*	*d.*	*Certification*

175

e. Other

No information provided.

Additional information is necessary.

15. COMPLIANCE WITH APPLICABLE STANDARDS:

a.	AAMI/ANSI	b.	ASTM
c.	ISO	d.	IEC
	CEN	[	UL
g.	Other		

UL certification mentioned.

16. COMPLIANCE FDA GUIDANCE

17. ANY OTHER ISSUE

a.	*Clinical*	*b.*	*Engineering*
c.	*Other*		

None

176

18. INFORMATION MATRIX

REVIEW ELEMENTS	YES	NO	DEFICIENCY
Ad ministrative		Indications for use form	
Labeling		Warning statement	
Description			
Comparative Information		Sleeves/performance	
Performance Testing		No burst testing, no raw data	
Environmental Testing		No EMC/electrical safety	
Clinical Testing		*NIA*	
Animal Testing		*NIA*	
Biocom patibility Testing		No	
Sterility Testing		*NIA*	
Packaging & Shelf Life Testing		No packaging information	
Software Testing		*NIA*	
Special Features			
Standards/G uidance			
ANY OTHER ISSUE			
Recommendation: AI			
Letter			
COMMENTS:			

FOR DCRND USE ONLY

DCRND/CSPG 510(K) SCREENING CHECKLIST

Device: Vaso Press System		K974393
Submitter: Britt Corp., Inc. Manufacturer: Britt Corp., Inc.		
DATES: Original Submission: 11/18/97 Received in ODE: 1 1121/97 Received in CSPG: 1 1/24/97 Reviewed: 12/1/97		Review Cycle 1
QUESTION	Yes	No
A. Is the product a device?	Yes	
B. Is the device exempt from 5lO(K) by regulation or policy?		No
C. Expedited Review Status: Requested by Sponsor?		No
D. Expedited Review Status: Identified by DCRND?		No
E. Expedited Review Status: Granted by DCRND?		No
F. Has this device been the subject of a previous NSE decision?		No
If yes, does this new 51O(K) address the NSE Issues (e.g., performance data, indications for use, etc.)		
G. Has the sponsor been the subject of an integrity investigation?		No
If yes, has the ODE Integrity Officer given permission to proceed with the review?		

Administrative Reviewer Signature: J.4L tt p J

Date: 1,/!)

179

DCRND/CSPG 510(K) SCREENING CHECKLIST

Device: Vaso Press System	K974393		
Submitter: Britt Corp., Inc.			
Listed Below Are Items Which Should be Included in a Submission *UNDERLINE MISSING & NEEDED INFORMATION*	YES	[redacted]	TEMS NEEDED & ISSING
I. General Information: a) trade name, b) common name, c) establishment registration , d) address of manufacturer, e) address of submitter, f) class, code g) CFR #, h) new or modification, i) predicate device, j) truth and accurate statement, k) indications for use statement (separate page)	No	[redacted]	o ndication orm separate age)
la. Reason for Submission:	Yes	[redacted]	
2. SMDA Requirement: 510(k) Statement	Yes	[redacted]	
2a. SMDA Requirement: Class III Certification & Summary (if Class III)	NA		
3. Indications for Use:	Yes	[redacted]	
4. Proposed Labeling: a) package insert, b) statement of intended use, c) advertisements or promotional material, d) instructions for use, e) MRI compatibility (if claimed), f) predicate device labeling	Yes	[redacted]	
5. Description (or Modification): a) device description with components, b) method of operation, c) design goals/validation, d) diagrams, e) engineering drawing, f) photographs, g) operator's manual, h) performance specifications, i) material specifications, j) modifications, k) safety features	Yes	[redacted]	
6. Table of Comparison- Similarities and Differences to Named Legally Marketed Equivalent Device: a) physical characteristics and functionality, b) labeling, c) intended use, d) anatomical sites, t) performance/environmental testing: in-vitro (EMC, electrical safety, mechanical testing, pressure, flow, failure mode), animal data, clinical data (test protocol, pass/fail criteria, blood data, hemolysis, results, analysis and summary, literature reference)	Yes	[redacted]	
7. Biocompatibility: a) list of component materials, b) list of patient-contacting material, c) biocompatibility testing of patient-contacting, final sterilized, and aged product, d) test protocol, e) pass/fail criteria, f) test results, g) toxicology profile, h) certification , i) reference standards	Yes		
8. Sterilization, Packaging and Shelf-Life: a) sterilization method (EtO, radiation, steam, autoclaving, etc.), h) SAL, c) packaging, d) pyrogen content, e) ETO residues, f) radiation dose, g) cleaning & disinfection , h) shelflife data	yes		
9. Software Validation & Verification: a) hazard analysis, b) level of concern, c) software requirements, d) development documentation, e) test reports, f) verification & validation, g) certification	NA		
10. Conformance with ODE/DCRND Guidelines and Other International/National Standards (IEC 601, UL 2601, IS0-10993, etc.):			

Items shaded under "No" are necessary for all submissions. Any checks in the last (Needed & MISSING) column requires resubission.

Passed Screenmg: Yes V No: Reviewer: [signature] Date: [illegible]

CSPG S IOK Check List; September 18, 1997

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

November 23, 1997

BRITT CORP., INC.
45 EAST MAIN ST., SUITE 204
FREEHOLD, NJ 07728
ATTN: J. JAMES BRITTON

510(k) Number: K974393
Received: 21-NOV-97
Product: VASO PRESS SYSTEM

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this SlO(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your SlO(k) as soon as possible. Also if you have not included your SlO(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(l) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

1 of 8

K974393

BRITT CORP

P.O. Box 547 • 45 E. Main St. Suite 204 • Freehold, NJ 07728
Phone (908) 863-1400 Fax (908) 863-1603

November 18, 1997

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Attn. Document Control Clerk
Re: 51O(k) PREMARKET NOTIFICATION

Pursuant to section 510(k) of the Federal Food, Drug, and Cosmetic Act, prarkef.... notification information is enclosed for the following device:

Device Name: Intermittent Compression System
Trade Name: Vaso Press System
Common Name: Intermittent Compression Unit and Compressible Limb sreeve ;
Classification Name: 870.5800 Compressible Limb Sleeve
Device Class: Class II
Classification Panel: Cardiovascular
Perfo rmance Standards: There are no performance standards for this system.
Facility Add ress & Establishment Registration Num ber:

Britt Medical Products a Division of Britt Corp.
45 East Main Street, Suite 204
Freehold, NJ 07728
Registration Number: 2249054

Reason For Submission: The Vaso Press System is a new device for Britt Medical Products but similar in form, function and design to existing products currently marketed by several companies.
Contact Information:

Name: J. James Britton
Address: Britt Medical Products
45 East Main Street, Suite 204
Freehold, NJ 07728
Telephone: (732) 863-1400
Fax: (732) 863-1603

Should additional information be required, please ontact me immediately.

Sincerely,

J. James Britton
President

II

161

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: NOVMEBER lB, lQg?

FDA Document Number: UNKNCMN

Section A — Type of Submission

☒ 510(k)	O IDE	O PMA	O PMA Supplement - Regular
D 510(k) Add1 information	O IDE Amendment	O PMA Amendment	O PMA Supplement - Special
	O IDE Supplement	O PMA Report	O PMA Supplement - 30 day
	O IDE R rt		O PMA Su lement - Panel Track

Section B1 — Reason for Submission — 510(k)s Only

☒ New device

D Additional or expanded indications

D Change in technology, design, materials, or manufacturing process

D Other reason (specify):

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D New device

D Withdrawal

D Additional or expanded indications

D Licensing agreement

D Labeling change:

- D Indications
- D Instructions
- D Performance Characteristics
- D Shelflife
- D Trade name
- D Other (specify below)

D Change in ownership

D Change in correspondent

☐ Other reason (specify):

D Change in design, component, or specification:

- D Software
- D Color Additive
- D Other (specify below)

D Process change:

- D Manufacturer
- O Sterilizer
- ☐ Packager

☐ Response to FDA correspondence (specify below)

D Request for applicant hold

D Request for removal of applicant hold

D Request for extension

D Request to remove or add manufacturing site

☐ Location change:

- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager
- ☐ Distributor

D Report submission:

- D Annual or periodic
- D Post-approval study
- D Adverse reaction
- D Device defect
- D Amendment

Section B3 — Reason for Submission — IDEs Only

D New device

D Addition of institution

D Expansion / extension of study

D IRB certification

D Request hearing

D Request waiver

D Termination of study

D Withdrawal of application

D Unanticipated adverse effect

D Emergency use:

- D Notification of emergency use
- ☐ Additional information

☐ Other reason (specify):

D Change in:

- D Correspondent
- D Design
- D Informed consent
- D Manufacturer
- D Manufacturing
- D Protocol - feasibility
- O Protocol - other
- ☐ Sponsor

D Report submission:

- D Current investigator
- D Annual progress
- D Site waiver limit reached
- D Final

D Response to FDA letter concerning:

- D Conditional approval
- D Cd approved
- ☐ Deficient final report
- D Deficient progress report
- D Deficient investigator report
- D Disapproval
- D Request extension of time to respond to FDA
- D Request meeting

D IOL submissions only:

- O Change in IOL style
- D Request for protocol waiver

FDA Document Number: UNKNOWN

Section C Product Classification

ProPuct code: JCM

C.F.R Section: 870 .5800

Device class:

D Class I II
OClass ill DUnclassified

Classification J\IJU!Ct eARDIOVASCUIAR

Section D Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

J0.1	2	3	4
	6	7	▮

Swnmary of. or statement concerning. safety and effectiveness data:

D 510(k) SUIDIDBJY attached

O(k) statement

Information on devices *to* which substantial equivalence is claimed:

510(k) Number	Trade or proprietaiy or model name	Manufacturer
K 874688	FIDWI RON HC	1 HUBTLEIGH TECHNOLOGY, INC.
2	2	2
3	3	3
4	4	4
▾	▾	
6	▮	▮

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Common or usual name or classification name:

COMPRESSIBLE LIMB SLEEVE

Trade or proprietary or model name	lvfodel nwnber
VASO PRESS SYSTEM	VP 100 and SLEEVES
2	2
3	3
4	4

FDA docwnent nwnbers of all rior related submissions (r ardless of outcome :

	2	3	4		
7	▮	9	10	11	12

Data included in submission: boratory testing D Animal trials D Hwnan trials

Indications (from labeling):

TRFATMENT OF VENOUS INSUFFICIENCY, INCLUDING VENOUS ULCERS AND EDEMA
TREATNENT OF PRIMARY AND SECONDARY LYMPHEDENA

183

.It Original D Add D Delete	FDA cstablisluncnt registration nwnbcr. NONE FOREIQ\l	anufacturcr 0 Contract manufacturer	D Contract sterilizer D Reoackager / relabeler
Company / Institution name: CATHAY CONSOLIDATED			
Division name (if applicable):		Phone number (include area code): (886 2) 551 8180	
Street address: lB, No. 11, BAO HONG ROAD, XIN TIEN		FAX number (include area code): (886 2) 571 8868	
City: TAIPEI XIEN	State / Province:	Cotmtry: TAIWAN	ZIP / Postal Code:
Contact name: ANTHCNY C.F. LIU			
Contact title: PRESIDENT			

'JII Original D Add D Delete	FDA cstablisluncnt registration number:	anufacturer D Contract manufacturer	D Contract sterilizer D Reoackager / relabeler
Company / Institution name: SEAL TECH			
Division name (if applicable): P.I. INC.		Phone number (include area code): (JI"I' :l) 744-8000	
Street address: 215 Ra::KY IDUNTAIN ROAD		FAX number (mclude area code): (423) 744-1364	
City: ATHENS	State / Province: 'IN	Country: USA	ZIP / Postal Code: 37371-1067
Contact name: JOHN AVERY			
Contact title: PRESIDENT			

D Original D Add 0Delete	FDA cstablisluncnt registration nwnbcr.	DManufacturer DContract manufacturer	D Contract sterilizer D Reoackaer / relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (mclude area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

FDA Document Number:

Section G Applicant or Sponsor

Company / Institution name: BRITI' CORP., INC	IDA establislunent registration nwnber: [redacted] (b)(4) Commercial Confidential
Division name (if applicable) 13RITI' MEDICAL PIDDOCI'S	Phone number (mclude area code): (732 863-1400
Street address: 45 EAST MAIN STREET, SUITE 204	FAX nwnber (mclude area code): (732 863-1603

City: FREEHOID	State gjovince:	Country: USA	ZIP /J>osl,_Corle: 07728

Signature:

Name: J.-)JAMEs BRITTON

Title: PRESIDENT

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company / Institution name:

Division name (if applicable):	Phone nwnber (mclude area code): (
Street address:	FAX nwnber (mclude area code): (

City:	State / Province:	Country:	ZIP / Postal Code:

Contact name:

Contact title:

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

TABLE OF CONTENTS

/b

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1. GENERAL INFORMATION

1.1 Applicant

Date: November 18, 1997
Name: J. James Britton
Address: Britt Corp., PO Box 547, 45 East Main Street, Suite 204
Freehold, NJ 07728

Contact Person: J. James Britton
Phone Number: (732) 863-1400, Fax (732) 863-1603

Signatu \OJ

1.2 Trade Name

Vaso Press System- The Vaso Press System consists of a pneumatic controller (pump) that supplies an air source to inflate extremity sleeves (garments).

- Model Number VP-100- Vaso Press Pump
- Model Number VP-101- Half Leg Uniform Compression Sleeve
- Model Number VP-102- Full Leg Uniform Compression Sleeve
- Model Number VP-120- Full Arm Uniform Compression Sleeve
- Model Number VP-201-Half Leg Segmental Sleeve
- Model Number VP-202-Full Leg Segmental Sleeve
- Model Number VP 220-Full Arm Segmental Sleeve
- Model Number VP-301-Half Leg Gradient Segmental Sleeve
- Model Number VP-302-Full Leg Gradient Segmental Sleeve
- Model Number VP-320-Full Arm Gradient Segmental Sleeve

1.3 Common Name or Classification Name

Common Name: Compressible Limb Sleeve
Intermittent Compression Unit (Anti-Embolism Pump)
Classification Name: 870.5800 Compressible Limb Sleeve

1.4 Establishment Registration Number: #2249054

1.5 Facility Address

Britt Medical Products a Division of Britt Corp.
PO Box 547
45 East Main Street, Suite 204
Freehold, NJ 07728

1.6. Section 513 Device Classification

1.6.1 Classification

This intermittent compression system that consists of a controller (pump) and compressible limb sleeves which are a Class II device.

1.6.2 Classification Panel

The panel to review this device is the cardiovascular panel.

1.7 Reason for Premarket Notification

The Vaso Press System is a new device for Britt Medical Products but similar in function and design to existing products currently marketed by several companies.

1.8 Predicate Device Description

This device is similar in function and application to devices that are currently marketed. The products consist of pneumatic pumps (controllers) that supply an air source to a compressible limb sleeve(s) that apply pressure to an extremity which will assist in moving extra-cellular fluids into the venous or lymphatic system. The pump is a compact device that inflates the sleeve to a pressure that has been recommended by a clinician. The products are used primarily in the home and depending on the degree of swelling can be used up to 2 hours per day.

1.8.1 Predicate Device Name

Flowtron HC, Model Number AC200HC and associated garments (sleeves) by Huntleigh Healthcare
Jobst Extremity Pump Home Model 7000 by Beiersdorf Jobst

1.8.2 Predicate Device Company

Huntleigh Healthcare
227 Route 33 East
Manalapan, NJ 07726

Beiersdorf Jobst Inc.
5825 Carnegie Blvd.
Charlotte, NC 28247-1048

1.8.3 Predicate Device 51O(k)#

Huntleigh's Flowtron HC K#874688. A copy of the product literature is included in Appendix A along with the 51OK.

1.9 Federal Food, Drug, and Cosmetic Act Compliance

There are no performance standards published for these devices.

2. SMDA Information

2.1 51O(k) Statement

A 51O(k) Statement is included in Appendix J.

2.2 Truthful / Accurate Statement

A Truthful and Accurate Statement, as required by 21 CFR 807.87(j), is provided in Appendix I.

3. INTENDED USE/PROPOSED LABELING

3.1 Statement of Intended Use

The Vaso Press Intermittent Compression System is used in the treatment and management of venous and lymphatic disorders. Depending upon the preference of the clinician they may choose a single uniform compression sleeve, segmental sleeve or a gradient sleeve

The controller provides cycles of compression at a selected pressure which inflate a single or three chamber sleeve. The three chambered sleeve provides a segmental uniform compression or a gradient pressure with the highest pressure most distal on the extremity.

3.2 Device Labels

Preliminary device labels are found in Appendix B.

3.3 Device Labeling

Preliminary device labeling, Operating Instructions is found in Appendix C.

3.4 Advertisements and Promotional Literature

Preliminary advertisement and promotional literature are located in Appendix D.

4. DEVICE DESCRIPTION

4.1 Physical Description

The air controller is a small and compact pump that provides an air source to inflatable limb sleeves.

4.1.1 Description

Depending upon the etiology, a prescription for Qne or two sleeves may be given. A pressure range is suggested by the clinician and the patient is instructed on the proper use and recommended treatment times. The sleeves are placed on the extremity and secured by a zipper closure so that the pressure derived from the controller is distributed over the extremity.

Once the sleeves are positioned they are attached to the controller by a connecting hose The pump is then turned on and the pre-selected pressure is delivered to the extremity by the air pressure in the sleeve(s)

The cycle timing for the inflation of the sleeves is preset to provide 90 seconds of compression on one sleeve and then 90 seconds on the other sleeve if a bilateral use has been prescribed.

4.1.2 Specifications

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

4.2 Photographs

Photographs of the products are found in Appendix E.

4.3 Significant Changes / Modifications from Predicate Device

There are no significant changes or modifications that would effect the safety or effectiveness of this device compared to the predicate devices.

4.4 Accessories

The sleeves that are used with the controller are manufactured from polyurethane impregnated nylon and have the following physical description:

SLEEVE SIZES FOR UNIFORM, SEGMENTAL AND GRADIENT SEG.

				Dimensions					Inserts	
Descri12tion	Single	Segment.	Gradient	L	W	F	H	S	A	B
Half Leg	VP 101	VS 201	VS 301	19.75	23	12.5			6	3.5
Full Leg	VP 102	VS 202	VS 302	30	26.5	12.5			7	3.5
Full Arm	VP 120	VS 220	VS 320	26			14.5	22.5	5	2

5. COMPARATIVE INFORMATION

5.1 Equivalent Device Information

Name: Flowtron HC
Status: The Huntleigh Flowtron has a 51OK
510(k) #: K874688
Name: Jobst Extremity Pump Home Model
Status: The Jobst Home Model is a predicate device

5.2 Comparison Table

The following table displays the similarities and differences of the new device to the legally marketed device to which equivalency is claimed.

Characteristic Compared	510(k) DEVICE FLOWTRON HC	Proposed Device Vaso Press
Product Labeling	Similar	(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data
Intended Use	Enhancement of lymphatic and venous flow.	
Physical Characteristics	11"L x 5"W x 4"H Power: 110-130 Volts Case Material High Impact ABS Pressure Range 30-90 mmHg Cycle Time: 90 seconds inflation 90 seconds deflation	
Anatomical Sites	Application of the sleeves are either on the leg or arm	
Target Population	Classed as home medical equipment and therefore is for use by patients who are primarily at home.	
Safety Characteristics	UL 544	

5.3 Performance Testing Subject Device

Test data is provided in Appendix F.

6. BIOCOMPATIBILITY ASSESSMENT

The sleeve material does not come in contact with the patients skin therefore no biocompatability assessments are provided.

7. STERILIZATION INFORMATION

The VASO PRESS SYSTEM is provided non-sterile.

The VASO PRESS SYSTEM is not intended for sterilization. Instructions for cleaning, disinfecting is as follows:

CLEANING INSTRUCTIONS: The outside case of the air controller is made from high impact ABS plastic and should be cleaned using a damp cloth and mild detergent. Hypocarbonate and phenol based cleaning solutions should never be used as they cause the case material to deteriorate.

The sleeve may be hand washed in luke warm water using a mild detergent.
CARE MUST BE TAKEN NOT TO SUBMERGE THE TUBING IN WATER
DO NOT DRY CLEAN THE SLEEVES
DO NOT IRON
DO NOT AUTOCLAVE

8. SOFTWARE VALIDATION & VERIFICATION

Does not apply to this device.

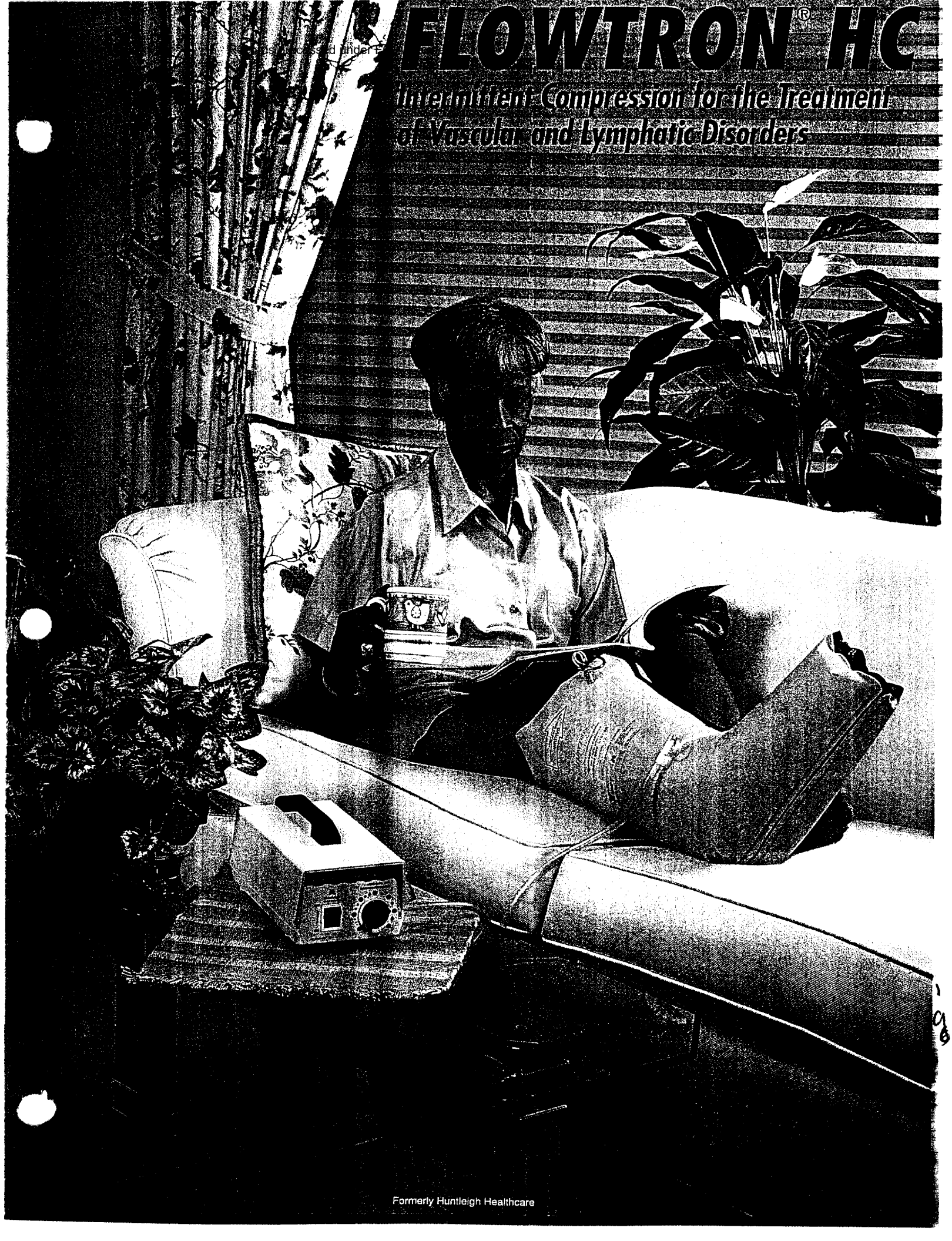
9. SPECIFIC STANDARDS & GUIDANCES

There are no standards or guidance documents on intermittent compression systems for the treatment of venous and lymphatic disorders. For reference a recent survey by the Agency for Health Care Policy and Research, Office of Health Technology Assessment is included in Appendix G.

Appendix A. Predicate Device 51OK

FLOWTRON® HC

Intermittent Compression for the Treatment of Vascular and Lymphatic Disorders



Formerly Huntleigh Healthcare

FLOWTRON® HC from HNE Jfl' ealth.are

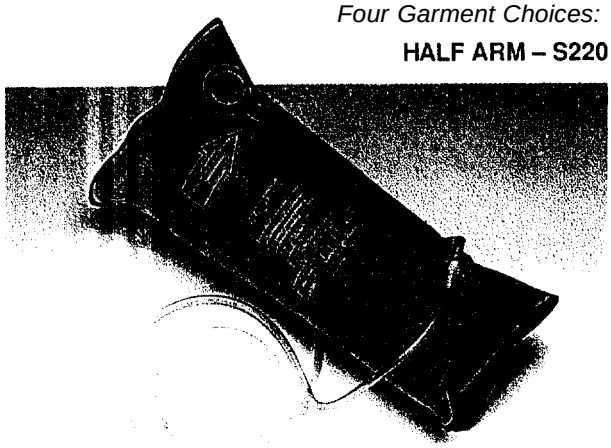
Intermittent Compression System

- *ate, effective treatment enhances lymphatic and venous* f/i:l'W.
- *Promotes increased circulation by simulating natura l rm.1sch contractions.*
- *Lined garments with full length zippers are durable, comfortable, and easy to use.*
- *Lightweight, portable pump with single pressure control.*
- *Cycle time preset at 90 seconds inflation and 90 seconds deflation.*
- *Ideal for home use.*

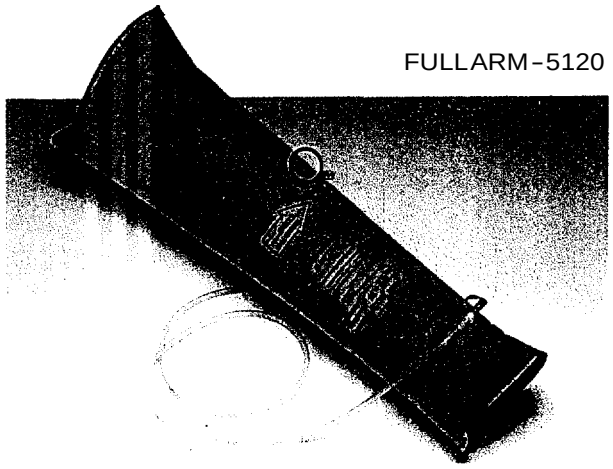
FLOWTRON - AC200HC

A val/able In Four Garment Choices:

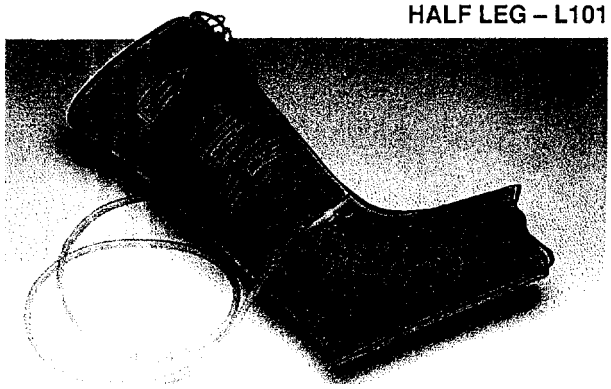
HALF ARM – S220



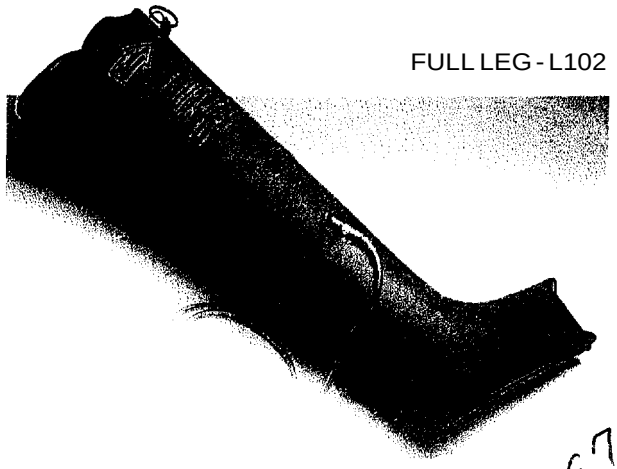
FULL ARM - 5120



HALF LEG – L101



FULL LEG - L102



Technical Specifications • Pump

Model Number:	AC200HC
Power:	110-130v 60Hz
Size:	4x11x5inches
Weight:	3¥. lbs.
Pressure Range:	30-90mmHg
Approximate Cycle Time:	90 seconds inflation 90 seconds deflation

Ordering Information

AC200HC Single Chamber Intermittent Compression Pump

L101 Half Leg Garment (19¥/ length)

L102ES Full Leg Extra Short Garment (27" length)

L102S Full Leg Short Garment (30" length)

L102M Full Leg Medium Garment (33' length)

L102Lfull Leg Long Garment (36V/ length)

L102EL Full Leg Extra Long Garment (381// length)

S120 Full Arm Garment (30¥.' length)

S220 Half Arm Garment (20" length)

Inflatable Inserts are available to increase garment circumference

For information on the full line of HNE Healthcare products including pressure relieving devices, compression systems and fetal/vascular Dopplers, please call 1-800-223-1218.

HNE HEALTHCARE
227 Route 33 East, Manalapan, NJ 07726
1-800-223-1218 • Fax: 908-446-1938

167

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

SEP 23 1988

Ms. Diane Distefano
Marketing Assistant
Huntleigh Technology, Inc.
227 Route 33 East
Manalapan, New Jersey 07726

Re: K874688
Flowtron AC 200/2
Regulatory Class: II
Dated: September 6, 1988
Received: September 15, 1988

Dear Ms. Distefano:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

Powered inflatable tube massagers are considered to be prescription devices in the United States. This means they can only be sold by, or on the order of, a licensed practitioner. No direct sales to the general public can be legally made. Such devices should be labeled in accordance with 21 CFR 801.109, copy enclosed.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device and permits your device to proceed to market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or

its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

LJA. - C

Carl A. Larson, Ph.D.
Director, Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Ad•inistration
Center for Devices and
Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

SEPTEMBER 15, 1988

HUNTLEIGH TECHNOLOGY, INC.
ATTN: J. JAMES BRITTON
227 ROUTE 33 EAST
MANALAPAN , NJ 07726

D.C. Number K874688
Received 09-15-88
Product FLOWTRON AC200/2

The additional information you have submitted has been received.

We will notify you when the processing of your submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. I suggest that you contact us if you have not been notified in writing at the end of this ninety (90) day period before you begin marketing you device. Written questions concerning the status of your submission should be sent to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or me at (301) 427-8162

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

AUGUST 25, 1988

HUNTLEIGH TECHNOLOGY, INC.
ATTN: J. JAMES BRITTON
227 ROUTE 33 EAST
MANALAPAN, NJ 07726

Ref K874688
Product FLOWTRON AC200/2

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. This information should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

When your additional information is received by the Office of Device Evaluation the 90-day period will begin again.

If after 30 days the requested information is not received, we will stop reviewing your submission. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and the 90-day time period will begin again.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or me at (301) 427-8162.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

201

Huntleigh Technology Inc.

CORPORATE HEADQUARTERS
227 Route 33 East

(201) 446 0a i rm

Sept. 6, 1988

Robert Chissler
Food & Drug Admin.
Center fur Devices &
Radiological Healt h
Document Mail Center (HFZ-401)
8757 Georgia Ave.
Silver Spring MD 20910

Dear Mr. Chissler:

Enclosed is the information requested by the Office of Device Evaluation concerning Ref: K874688 Product: Flowtron AC 200/2. As discussed with Dr. Blanckwell , we have excluded the reference to our produt simulating natural muscle contractions comparable lo exercise.

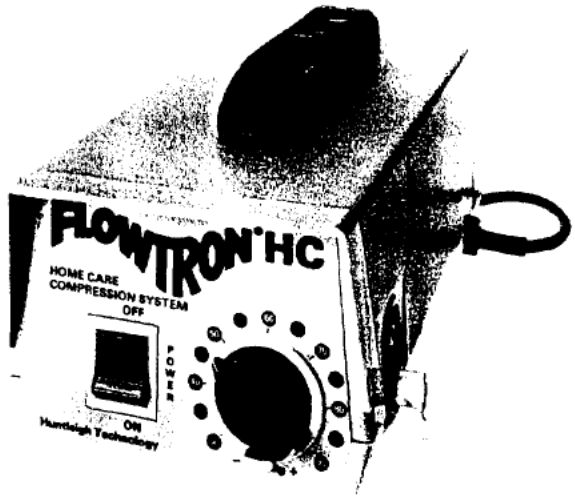
If I may be of further assistance, please feel free to contact me.

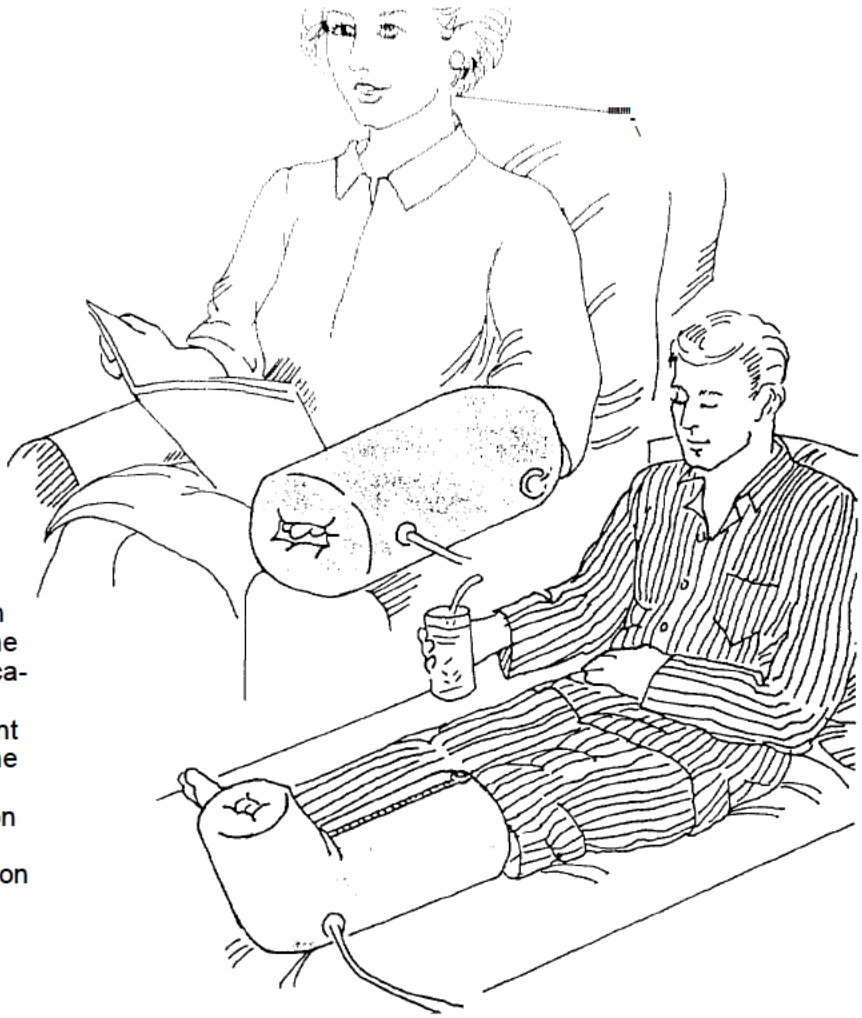
Sincerely yours,

Diane DislefcGo
Mkting. Asst.

FLOWTRON® HC

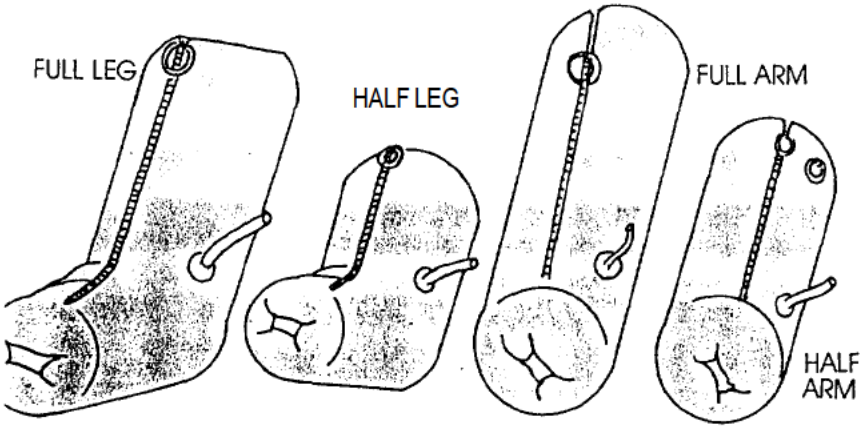
HOME CARE COMPRESSION SYSTEM





Home Care Intermittent Compression

Huntleigh Technology, with over 15 years experience in intermittent compression therapy, has now developed the Flowtron HC, a system designed specifically for application in the home environment. The system consists of a :ompact pump which intermittently inflates a garment rhat is applied to the extremities. The pressure within the arment is controlled by a dial set at a recommended .dvel. The entire cycle time is preset at 90 seconds inflation and 90 seconds deflation. By alternating the pressure, blood flow is stimulated, resulting in improved circulation and healing.



- Non-Invasive
- Natural Action
- Practical and Simple to Use
- Ideal for Home Use

IMPROVING THE NATURAL FLOW

Intermittent compression assists venous and lymphatic flow where vascular problems exist. When ambulation is restricted or there is inJury to muscle, lymph vessels, or veins, fluid balance may be impaired.

Huntleigh's compression systems facilitate fluid movement by creating a pressure shift within the tissues. During the inflation phase of the system, excess fluid is gently pushed out of the tissue area and into the venous and lymphatic circulation. Once within the circulation, this extra fluid is more readily excreted by the body's natural mechanisms or functions.

Huntleigh Technology
227 Route 33 East, Manalapan, NJon2s
Toll Free: 800-223-12181h NJ (201) 446-2500

Huntleigh Compression Systems for non-invasive therapy in vascular and lymphatic disorders.

DEPARTMENT OF HEALTH AND BUMAN SERVICES Public Health Service

rood and Druq Adainistration
Center for Devices and
Radioloqical Health
8757 Georqia Avenue
Silver Sprinq, MD 20910

AUGUST 25, 1988

HUNTLEIGH TECHNOLOGY, INC.
ATTN: J. JAMES BRITTON
227 ROUTE 33 EAST
MANALAPAN, NJ 07726

Ref K874688
Product FLOWTRON AC200/2

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. This information should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
8757 GeQ,Fgia Avenue
Silver Spribg, Maryland 20910

When your additional information is received by the Office of Device •aluation the 90-day period will begin again.

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Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

8011

Huntleigh Technology Inc.

CORPORATE HEADQUARTERS
227 Route 33 East
Manalapan, NJ 07726
(201) 446-2500 • 800-223-1218
Telex 132819

Sept. 6, 1988

Robert Chissler
Food & Drug Admin.
Center fur Devices &
Radiological Health
Documen L Mai l Center (HFZ-401)
8757 Georgia Ave.
Silver Spring MD 20910

Dear Mr. Chissler:

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If I may be of further assistance, please feel free to contact me.

Sincerely yours,

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Diane Distef o
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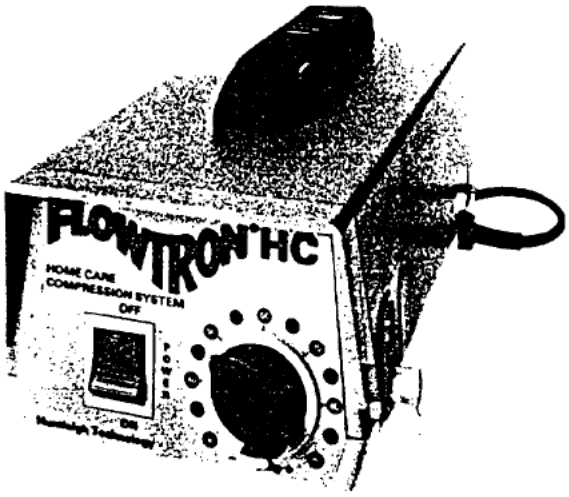
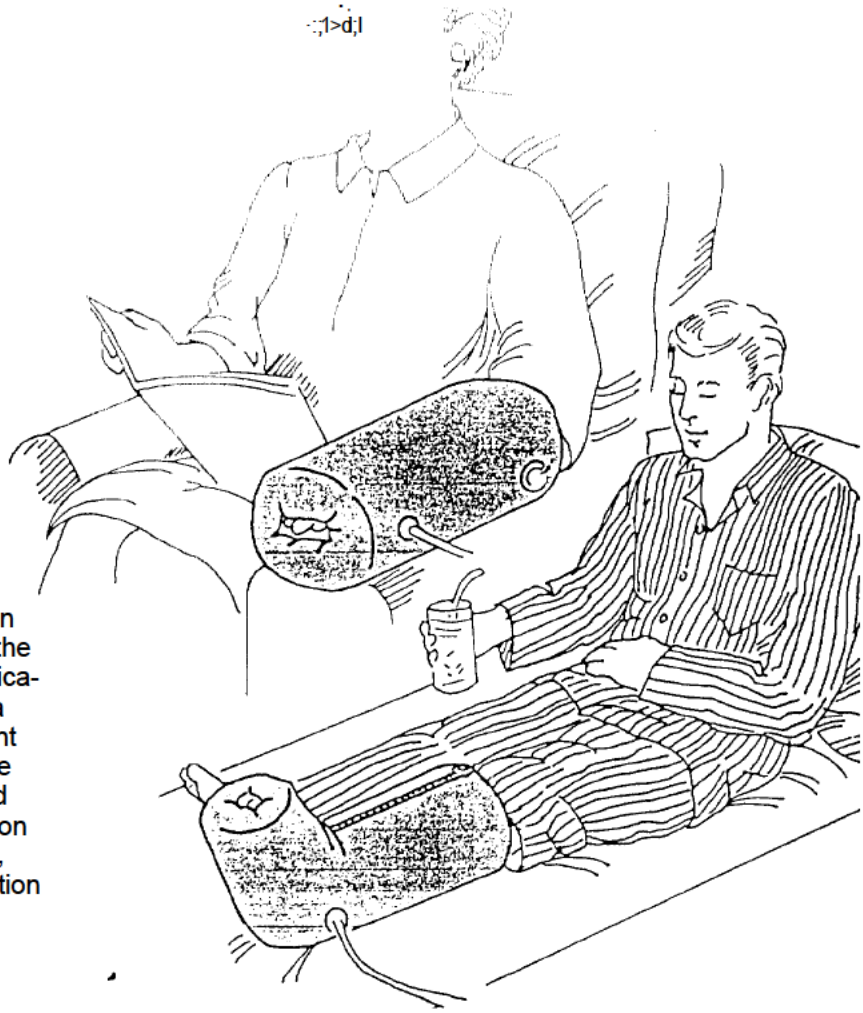
FLOWTRON® HC HOME CARE COMPRESSION SYSTEM





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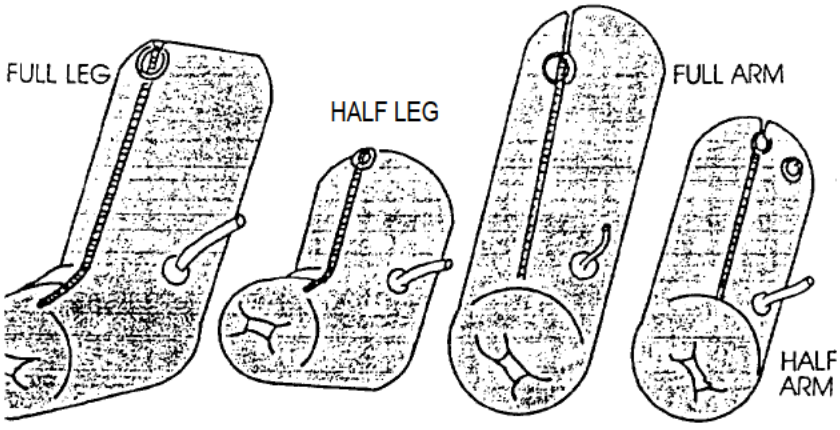

- Non-Invasive
- Natural Action
- Practical and Simple to Use
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Huntfeigh
Technology
227 Route 33 East. Manalapan. NJ 07726
Toll Free: 800-223-1218/In NJ (201) 446-2500

Huntleigh Compression Systems for non-invasive therapy in vascular and lymphatic disorders.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Adainistration
Center for Devices and
Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

JUNE 10, 1988

HUNTLEIGH TECHNOLOGY, INC.
ATTN: J. JAMES BRITTON
227 ROUTE 33 EAST
MANALAPAN, NJ 07726

D.C. Number K874688
Received 06-09-88
Product FLOWTRON AC200/2

The additional information you have submitted has been received.

We will notify you when the processing of your submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. I suggest that you contact us if you have not been notified in writing at the end of this ninety (90) day period before you begin marketing you device. Written questions concerning the status of your submission should be sent to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or me at (301) 427-8162

ncerely y

sler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

REG'D JUN 16 1988

207

Huntleigh Technology Inc.

CORPORATE HEADQUARTERS
227 Route 33 East
Manalapan, NJ 07726
(201) 446-2500 800-223-1218
Telex 132819

June 6, 1988

Food & Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Attention: Ms. Marie Schroeder

REFERENCE: K874688
PRODUCT: Flowtron AC200/2

Dear Ms. Schroeder:

Regarding our phone conversation this past week, I am supplying the additional information requested.

1. PRODUCT LITERATURE:

The literature initia y submitted is being withdrawn. This was used to market our products in the U.K. and other European countries. I have re-submitted the literature on the Flowtron HC which is our home care version and the primary product that we wish to market. Therefore, this application should be amended to include the AC200HC.

The products are similar but the HC version does not have a pressure gauge and the three prong ground plug has been eliminated. Please note reference to both products under specifications. Since all of our pneumatic pumps are doubly insulated, there is no compromise on electrical safety.

The pressure on the HC model is set by adjusting the dial to the indicated numerical setting.

2. GARMENTS AND MATERIAL:

Enclosed is a letter dated March 1, 1988 which addresses this question. There are four styles of garments as indicated.

.../2

Huntleigh echnology

204

3. CONNECTING HOSES:

The hoses to connect to the pump are made of PVC.

4. PRESSURE RANGE:

30 90 mrnHg.

5. COPY CHANGES:

From our last conversation, we have now eliminated the references to specific indications. We will submit, at a later date, documentation that we feel is sufficient so that specific claims can be made. In the meantime, the indication will read:

"Reduces lymphatic, venous and traumatic edema in the extremities by enhancing natural biood and lymphatic fluid flow."

6. CLEANING INSTRUCTIONS:

The cleaning instructions will read as follows. These are silkscreened on the inside of each garment.

Cleaning

Do not dry clean. Do not iron. Handwash in lukewarm water using normal detergent or soap powder. Take care to leave the end of the tube out of water while washing. When dry the appliance may be wiped over with antiseptic lotion or cream.

Sterilization

Gas sterilization is suitable for these appliances. The temperature should not exceed 125 degrees Farenheit (51 degrees centigrade).

I hope the above information is sufficient to complete the 510K notification. If you do need any further clarification, please contact me.

Sincerely yours,

J. James Britton
Executive Vice President

JJB/mes
enc.

FLOWTRON® INTERMITTENT COMPRESSION SYSTEM

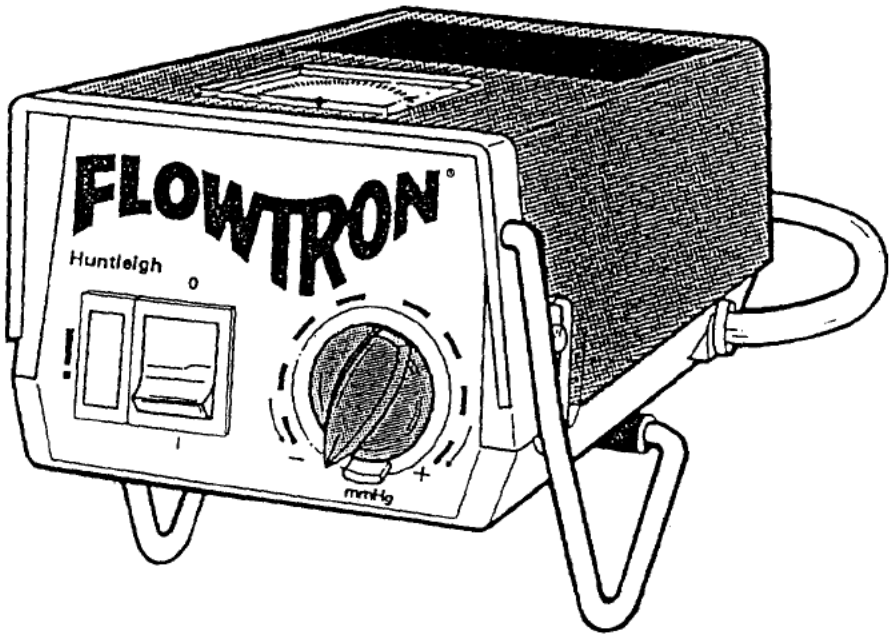
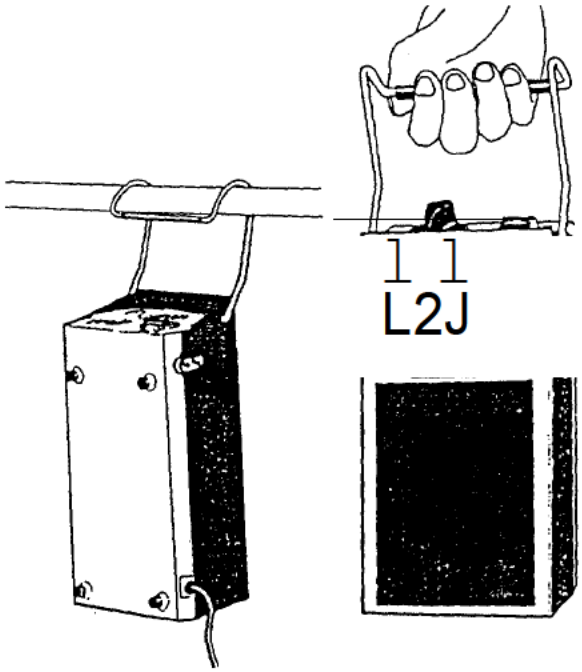


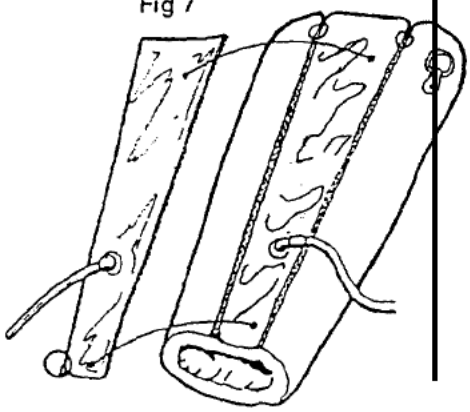
Fig 1,--



L2J

Use of inserts to increase circumference of garment.

Fig 7



OPERATION

1) Site the pump (Fig 1) on a suitable flat surface or hang on rail/armrest as illustrated.

2) Connect to supply and switch on before connecting garments.

3) Both indicator lamps should illuminate (Flg 2).

4) Before fitting garment cover the limb with gauze or similar material to prevent excesive perspiration.

5) Connect the garment or garments to the pump outlets (Fig 3), after checking garment pull ring is inserted. When using one garment only, ensure that the other air outlet on the pump is closed using the stopper attached.

6) Should the garment be connected incorrectly or if there is a leak the red lamp will remain illuminated (Fig 4).

7) Adjust pressure control (Fig 5) to desired setting as indicated by pressure gauge (Fig 6).

8) Treatment should now commence for as long as required or is convenient.

9) IMPORTANT - Before removing the garment release the pull ring or [illegible] the pump allowing deflation.

Fig 2

Fig 3

Fig 4

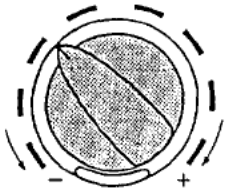


Fig 5

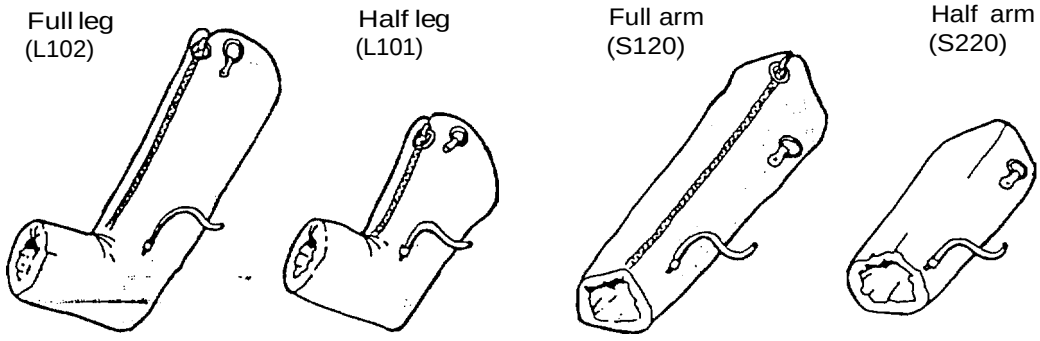
Fig 6

TECHNICAL SPECIFICATION

Flowtron Model AC 200/2

Power:	220-240V 50Hz 110-130V 60Hz 90 - 110V 50/60Hz	Cycle Time: (Total)	Fully Automatic 220 - 240V 3 mins 110 - 130V 3.3 mins 90 - 110V (50Hz) 4 mins 90 - 110V (60Hz) 3.3 mins
Size:	26 x 12 x 10cm		
Weight:	1.7Kg		
Pressure Range:	30 - 90mmHg	Indicators:	Power on; low air pressure; pressure gauge

Also incorporating multi-purpose stand/ hook and carry handle.



A range of inflatable extension inserts (Fig 7) are available to increase circumference of L101 (Half leg), L102 (Full leg), 5120 (Full arm) and 5220 (Half arm). When ordering insert pieces, subsititute IP for L or 5 prefix in order code numbers.

TROUBLE SHOOTING GUIDE

If red lamp remains illuminated:

a) check for loose garment connection;.
b} ensure that garment pull ring is fully inserted;
c) if using one garment, ensure other pump outlet is plugged with the stopper provided.
d) try replacement garment;
e} if no improvement, please return to your local service centre.

N.B. Please remember that the unit takes approximately 10 mins to achieve normal running pressure. After this time the red lamp should be extinguished. Momentary illumination during changeover may occur, but does not indicate a fault.

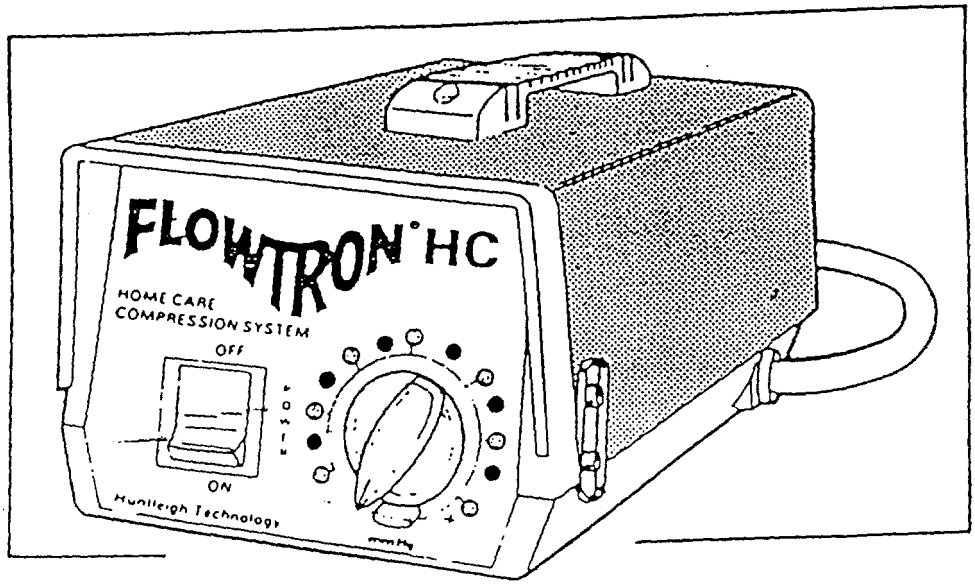
213

fLOWTRON HC

Huntleigh

INTERMITTENT COM.PRESSION SYSTEM

OPERATING INSTRUCTIONS
TREATMENT NOTES

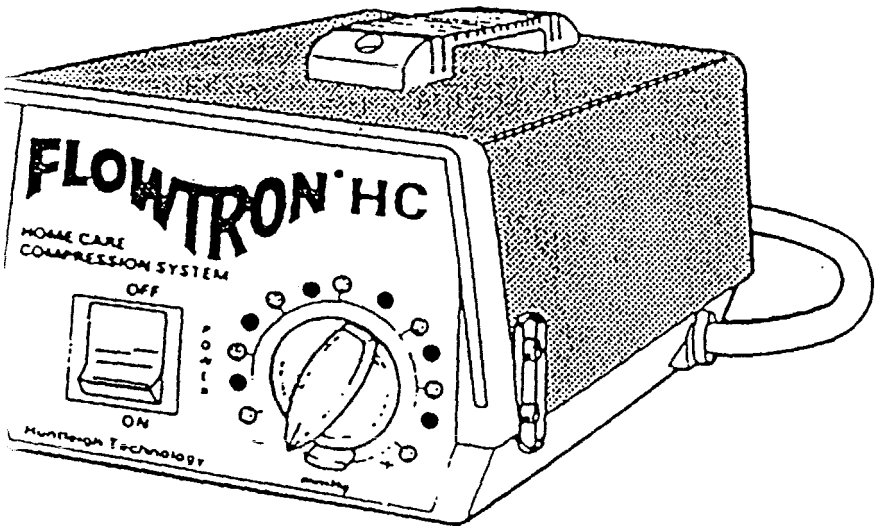


The Natural Solution to Venous and Lymphatic Disorders

D13

FLOWTRON HC

INTERMITIENT COMPRESSIO N SYSTEM



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Use ol insens to increase circumf erence of ga rment.

Fig 7

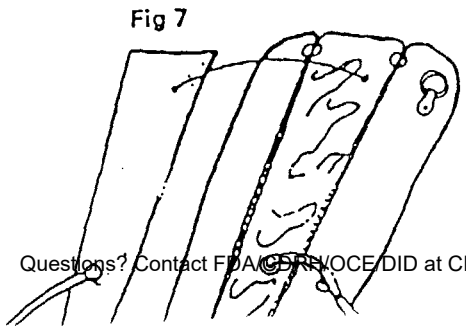


Fig 2

Fig 3

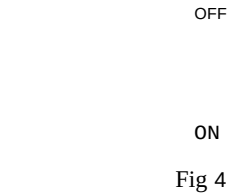


Fig 4

USER INSTRUCTIONS

User Instructions
Check function of equipment and integrity of enclosure prior to each use.

No periodical preventive technical maintenance is required. In case of failure contact your local dealer.

Pump Unit Cleaning lnsruction
To clean pump unit, wipe with a damp cloth and a mild detergent.

Garment Cleaning Instruction
Do not dry clean. Do not iron. Hand wash in lukewarm water using normal detergent or soap powder. Take care to leave the end of the tube out of the water while washing. When dry the appliance may be wiped over with antiseptic lotion or cream.

Sterili$8tiOn
Gas sterilisation is suitable for these applia nces. The temperature should not cxcee<l 125°F {51°CI.

Technical information concerning our products can be obtained from Huntleigh Technology pie. *or* from your local distributor.

USER MAINTENANCE

1) Always switch off (Fig. 4) and unplug this unit immediately after usi

2l Do not use while bathing.

3) Do not place or store product where it can fall or be pulled into a tub sink.

4) Do not place in or drop into water or other fluid.

5) Do not reach for a product that has fallen into water. Unplug immedia H

WARNING

TO REDUCE THE RISK OF BURNS.
ELECTRDCUTION, FIRE OR INJURY
TO OTHER PERSONS.

1) Use this unit only for its intended use as described in this manual.

21 Never operate this product if it has a damaged *cord or* plug, if it is not working properly, if it has beem 'dropped *or* damaged, or dropped intc water. Return unit to service c=entre *for* examination and repair.

3) Keep the cord away from heated surfaces.

4) Never drop *or* insert any object into any opening *or* hose.

5) Do not use outdoors *or* operate where aerosol (spray) producrs are used *or* where oxygen is being administered.

6) Possible explosion hazard if used in the presence of flammable anaesthetics.

Huntleigh Technology Inc.

CORPORATE HEADQUARTERS
227 Route 33 East
Manalapan, NJ 07726
(201)446-2soo • 800-223-1218
Telex 132819

March 1, 1988

Food & Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Ave.
Silver Spring, MD 20910

Attn: Mr. Robert I. Chissler
Premarket Notification Coordinator

Ref: K874688
Product: Flowtron AC200/2

Dear Mr. Chissler:

In reference to your letter dated February 3rd, and a telephone conversation with Marie Schroeder, we are submitting the additional information requested.

1. Cycle time - The cycle time on the Flowtron Air AC400 is one minute on and one minute off, while the submitted product Flowtron AC200/2 is one minute forty-five seconds on and one minute forty-five seconds off.

2. Garment Material Construction - Two types are used - the outer layer is made from a polyurethane nylon while the inner is a two-way stretch woven material. Construction is from the same material used in our previous SlOK submission K871271 - Flowpress Garments SQ301/302/320.

3. Standard - The pump AC200/2 is U.L. listed under their UL544 for medical devices, and is doubly insulated plus has a three prong hospital rade plug.

4. Claims - We are making claims for application in chronic lymphatic and venous disorders to reduce edema and improve circulation (similar to our application K871271 and K850190). These conditions are manifested by indications listed in the product literature. Enclosed is selected literature for reference.

luntleigh
chnology

I believe the foregoing supplies the information that you requested. Should you require any additional information or clarification, please contact me at 1-800-223-1218.

Very truly yours,

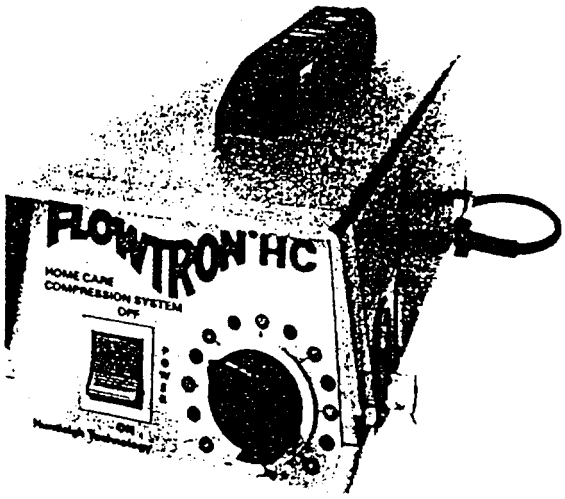
J. JAMES BRITTON
Executive Vice President

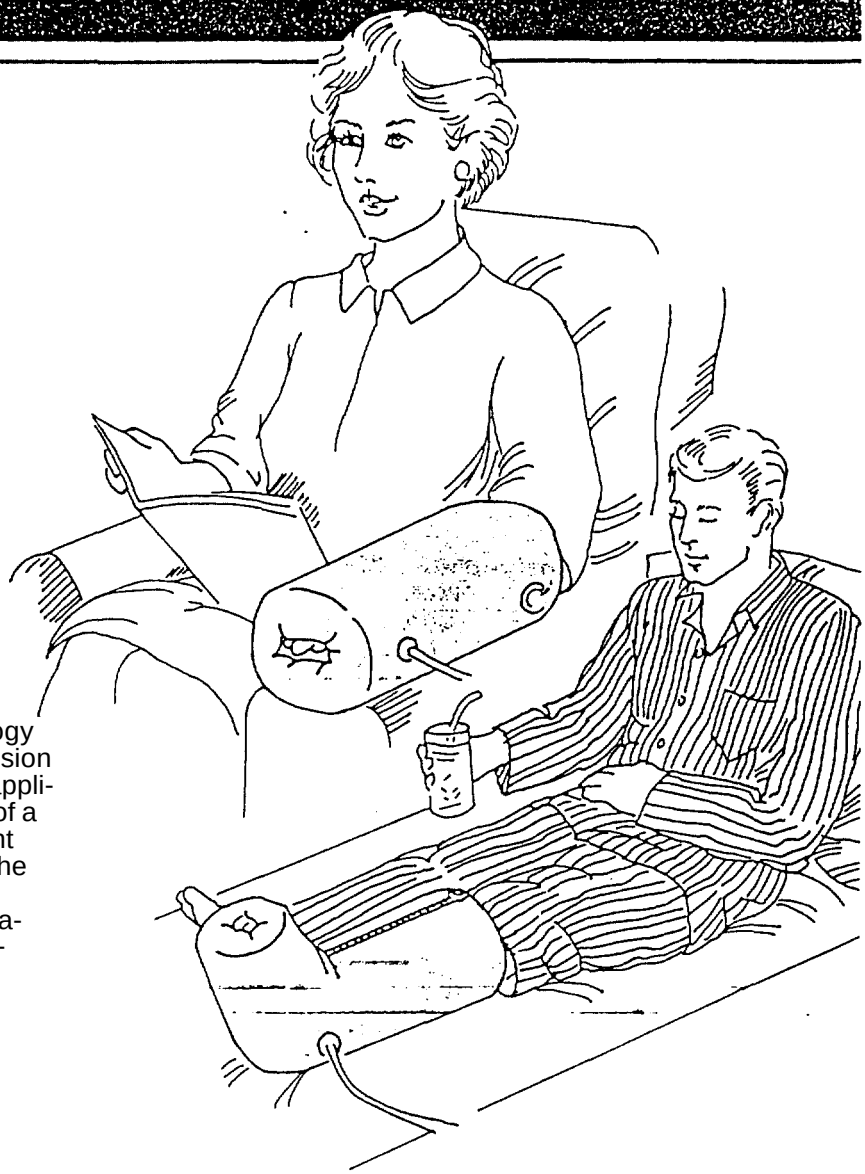
JJB:cm

Enclosures

217

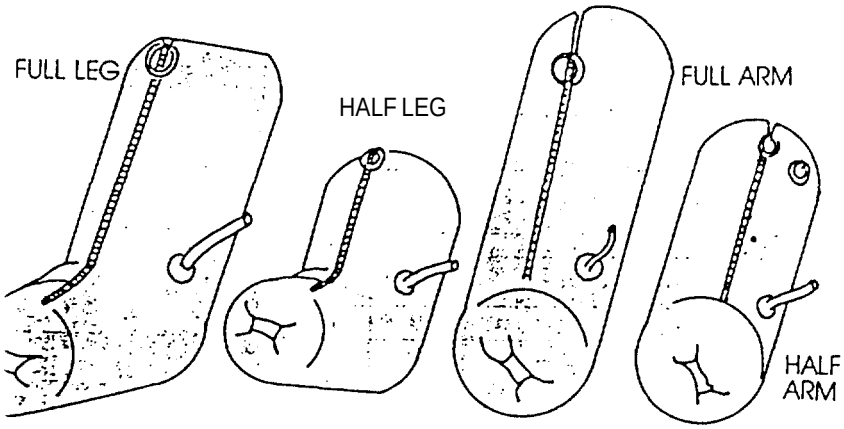
FLOWTRON® HC HOME CARE COMPRESSION SYSTEM





Home Care Intermittent Compression

Flowtron HC, a development from Huntleigh Technology with over 15 years experience in intermittent compression therapy. has now designed a system specifically for application in the home environment. The system consists of a compact pump which intermittently inflates a garment that is applied to the extremities. The pressure within the garment is controlled by a dial set at a recommended lever. The entire cycle time is preset at 90 seconds inflation and 90 seconds deflation. By alternating the pressure, blood flow is stimulated, resulting in Improved circulation and healing.



- Non-Invasive
- Natural Action
- Practical and Simple to Use
- Ideal for Home Use

Improving the Natural Flow

Intermittent compression increases venous and lymphatic flow where vascular problems exist. The process promotes better circulation by simulating natural musGle contractions comparable to walking or exercise.

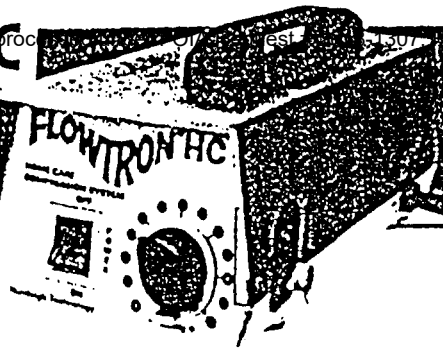
When ambulation is restricted or there is injury to muscle, lymph vessels or veins, fluid balance may be impaired. By imitating normal muscle contractions, Huntleigh's compression systems facilitate blood flow and gently force the excess fluid *from* the tissues back into the vascular system.

'if,ct

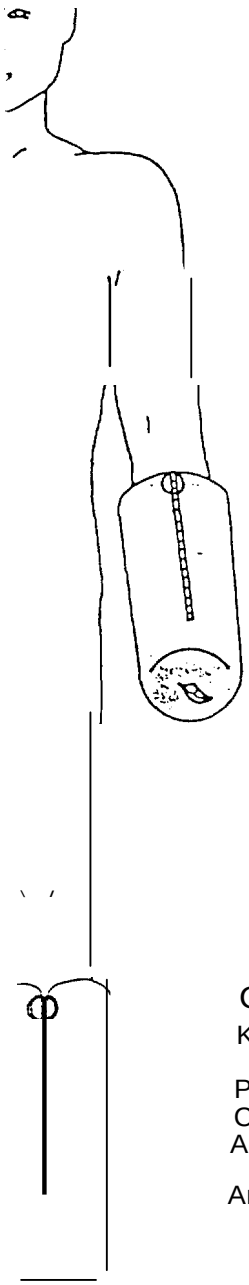
Huntleigh Compression Systems for non-invasive therapy in vascular and lymphatic disorders.

Huntfelgh
$ Technology
227 Route 33 East, Manalapan NJ07726
Toll *Free:* 800·223·1218. In NJ (201) 446-2500

FLOWTRON HC



HOME CARE COMPRESSION SYSTEM



Clinically Proven Effective and Safe

Lymphedema

Damaged lymph nodes, caused by surgical procedures and radiation therapy following a radical mastectomy,cause the limbs to be swollen, heavy and painful.

Intensive use *of* the inflatable full sleeve, supplemented by the use *of* made to measure elastic hosiery, will provide welcome and lasting relief.

"External pneumatic compression therapy can reduce significantly the girth and volume *of* a lymphedemotous limb:'

"Intermittent Compression represents a safe,non-invasive, highly effective.and inexpensive method *for* treating edema *of* the *leg:*[2]

Indicatio_ns:

Reduces lymphatic, venous and traumatic edema in the extremities by enhancing natural blood and lymphatic 4'lu in fl nw.

Contraindications:

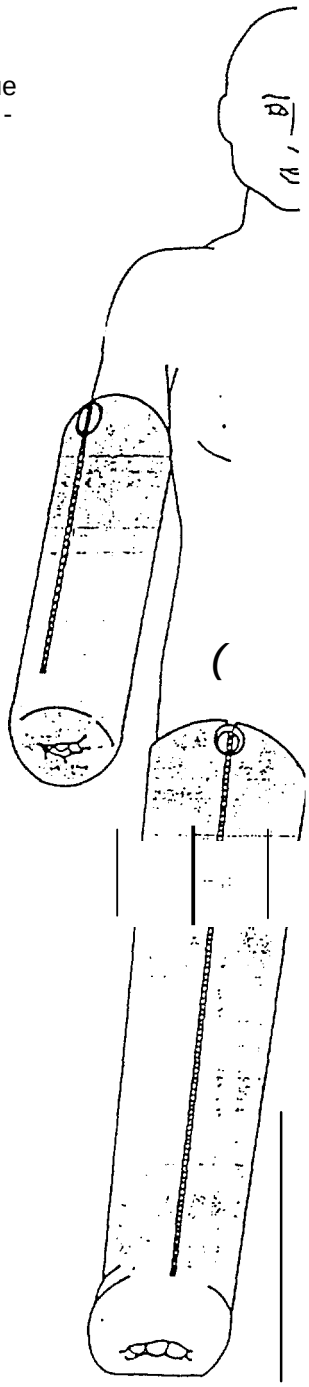
Known or suspected Dvr (deep vein leg clots)
Pulmonary edema
Congestive heart failure
Active. untreated infection (cellulitis. infected wound.etc.)
Any condition whereby on increase *of* fluid to the heart would be detrimental.

Vascular Insufficiency

If physical movement is restricted due to age *or* injury, the body's venous circulatory system becomes sluggish which can result in blood pooling *or* stasis. *It* is also possible for the valves located within the veins to become defective.leading to diminished venous *return.* More notable effects *of* this valvular Insufficiency are varicose ulcers and• stasis ulcers.

We now recommend routine use *of* intermittent compression *of* the calf in instances *of* popliteal and femoral venous repair, particularly when an interposition *or* bypass graft has been used.#[3]

Chronic leg ulcers benefit from pneumatic inter..: mittent compsion:



Specifications:

Model No.	AC200HC
Power:	110-130V 60 Hz
Size:	6 x 12*x* 10cm
Weight:	17 Kg (3.75 lbs.)
Pressure Range:	30-90 mmHg
Cycle Time:	Fully Automatic 90 seconds on- 90 seconds *of f*
Indicators:	Power on. Pressure dial

Also available:*AC20012.* Some specifications as above but with a pressure gouge and hospital grade plug.

DISTRIBUTED BY:

/BUOGRAPHY

es. *Jef fre-.* Ph.D.; et al. "Selection *of* Patients wilh Lymphedemo Compression -..oy-, The American Journal *of* Surgery.Vol. 133 (April 1978). 433.

J <;;/ M.D. Ph.D. "Jnlermiltenl Compression in the Monogemenl ol Swollen Le._. ...nd General Praclice·. PracfiliOner. 69. 1975.

Hobson II, Robert W.M.D.: el al. use *of* Jnlermlltenl Pneumatic Compression ol *the* Coif ifl femoral Venous Reconstruction .Surgery,Gynecology & Obslelrics. *Vol.* 159 (September 1984). 286.

Hozoriko .M.S..M.A.M.S..F.R.C.S..FJC.S..*ED.* otat.."Chronic Leg Ulcers The Effect *ot* Pnc·.Jmohc tntcrmittcnl Compression. The Practitioner. February 1981, Vol. 225 POQ<:IS 189·192

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

MAY 25, 1988

HUNTLEIGH TECHNOLOGY, INC.
ATTN: J. JAMES BRITTON
227 ROUTE 33 EAST
MANALAPAN, NJ 07726

Ref K874688
Product FLOWTRON AC200/2

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. This information should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

Then your additional information is received by the Office of Device .valuation the 90-day period will begin again.

If after 30 days the requested information is not received, we will stop reviewing your submission. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and the 90-day time period will begin again.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or me at (301) 427-8162.

Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Druq Adainistration
Center for Devices and
Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

MARCH 2, 1988

HUNTLEIGH TECHNOLOGY, INC.
ATTN: J. JAMES BRITTON
227 ROUTE 33 EAST
MANALAPAN, NJ 07726

D.C. Number K874688
Received 03-02-88
Product FLOWTRON AC200/2

The additional information you have submitted has been received.

We will notify you when the processing of your submission has. been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. I suggest that you contact us if you have not been notified in writing at the end of this ninety (90) day period before you begin marketing you device. Written questions concerning the status of your submission should be sent to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or me at (301) 427-8162

tL

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

Huntleigh Technology Inc.

CORPORATE HEADOUARTERS
227 Route 33 East
Manalapan, NJ 07726
(201) 446-2500 • 800-223-1218
Telex 132819

March 1, 1988

Food & Drug Administration
Center for Devices and Radiologqi al Health
Document Mail Center (HFZ-401)
8757 Georgia Ave.
Silver Spring, MD 20910

Attn: Mr. Robert I. Chissler
Premarket Notification Coordinator

Ref: K874688
Product: Flowtron AC200/2

Dear Mr. Chissler:

In reference to your letter dated February 3rd, and a telephone conversation with Marie Schroeder, we are submitting the additional information requested.

1. Cycle time - The cycle time on the Flowtron Air AC400 is one minute on and one minute off, while the submitted product Flowtron AC200/2 is one minute forty-five seconds on and one minute forty-five seconds off.

2. Garment Material Construction - Two types are used - the outer layer is made from a polyurethane nylon while the inner is a two-way stretch woven material. Construction is from the same material used in our previous 510K submission K871271 - Flowpress Garments SQJ01/302/320.

3. Standard - The pump AC200/2 is *U.L.* listed under their UL544 for medical devices, and is doubly insulated plus has a three prong hospital qrade plug.

4. Claims - We are making claims for application in chronic lymphatic and venous disorders to reduce edema and improve circulation (similar to our application K871271 and K850190). These conditions are manifested by indications listed in the product literature. Enclosed is selected literature for reference.

Huntleigh rechnology

227

I believe the foregoing supplies the information that you requested. Should you require any additional information or clarification, please contact me at 1-800-223-1218.

Very truly yours,

J. JAMES BRITTON
Executive Vice President

JJB:cm

Enclosures

227

DEPARTMENT OF HEALTH AND BUMAN SERVICES Public Health Service

Food and Drug Adainistration
Center for Devices and
Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

FEBRUARY 3, 1988

HUNTLEIGH TECHNOLOGY, INC.
'ATTN: J. JAMES BRITTON
227 ROUTE 33 EAST
MANALAPAN, NJ 07726

Ref K874688
Product FLOWTRON AC200/2

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. This information should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

hen your additional information is received by the Office of Device valuation the 90-day period will begin again.

If after 30 days the requested information is not received, we will stop reviewing your submission. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and the 90-day time period will begin again.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or me at (301) 427-8162.

rt L

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

924

DEPARTMENT OF HEALTH AND BUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

NOVEMBER 24, 1987

HUNTLEIGH TECHNOLOGY, INC.
ATTN: J. JAMES BRITTON
227 ROUTE 33 EAST
MANALAPAN, NJ 07726

D.C. Number K874688
Received 11-13-87
Product FLOWTRON AC200/2

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug and Cosmetic Act for the above referenced device has been received and assigned a unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. I suggest that you contact us if you have not been notified in writing at the end of this ninety (90) day period before you begin marketing your device. Written questions concerning the status of your submission should be sent to:

Food and Drug Administration
Center for Devices and
Radiological Health Off
ice of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or me at (301) 427-8162.

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

HEC'D rO V 27 1987

Appendix B. Preliminary Device Labels

Appendix B:

PRELIMINARY LABELING FOR THE VASO PRESS SYSTEM

LABELING FOR THE CONTROLLER

Controller Faceplate Label

VASO PRESS

Intermittent Compression

BRIIT
Medical Products

50 mmHg

ON OFF

30 mmHg
Low

80 mmHg
High

Controller Rear Label

BRITT MEDICAL PRODUCTS
A DMSION OF *BRITT* CORP
INTERMI'ITENT COMPRESSION SYSTEM
CONTROLLER Model Number VP 100

Caution: Do not use in the presence of flammable anesthetics.
UL AIR PUMP UL LIS1ED 3G40
SPECIFICATIONS: llOV/60 Hz
MADE IN TAIWAN

LABELING FOR 1HE SHIPPING CARTON

VASO PRESS

INTERMITTENT COMPRESSION SYSTEMS

VASO PRESS CONTROLLER

RE ORDER NUMBER: VP 100
BRIIT MEDICAL PRODUCTS
A DMSION OF *BRITT* CORP
45 EAST MAIN STREET FREEHOLD NJ 07728
TEL# (732) 863-1400 Fax # (732) 863-1603

227

LABELING FOR THE SLEEVE
(representative sample)

LABELING FOR THE HALF LEG SLEEVE

VASO PRESS

INTERMITIENT COMPRESSION SYSTEMS

HALF LEG

RE ORDER NUMBER: VP 101

BRITT MEDICAL PRODUCTS
45 EAST MAIN STREET SUITE 204
FREEHOLD, NJ 07728

TEL# (732) 863-1400, FAX# (732) 863-1603

MADE IN USA

228

Appendix C. Preliminary Device Labeling, Operating Instructions

Appendix C:

Preliminary Operating Instructions: Vaso Press Intermittent Compression System

Description and Operating Principle- Vaso Press is an intermittent pneumatic compression system for the treatment and management of venous and lymphatic disorder. By compressing the extremity increased venous and lymphatic flow is encouraged.

The system consists of an air controller (pump) and soft pliable compression sleeves. The controller supplies compression on a pre set timing cycle (90 seconds on followed by 90 seconds of deflation) which is intermittent at a selected pressure setting. The compression in the sleeves is transferred to the applied extremity encouraging the transfer of extra cellular fluids into the bodies natural drainage system (the venous and lymphatic system).

The Vaso Press System may be used on and by patients who suffer from lymphedema, radiation therapy or chemotherapy, venous edema following trauma or surgery, or venous leg ulcers.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or other licensed practitioner.

System Set Up and Operating Instructions- The Vase Press System is very easy to set up. The following steps should be followed:

1. Please read this instruction manual in its entirety before setting up.
2. Once the controller and sleeves have been removed form their packaging, plug the controller into an electrical outlet. Do Not Switch On.
3. Position the controller on any flat surface.
4. Connect the sleeve(s) to the controller outlet(s) by pushing the tubing onto the air outlet. If only one sleeve is used, plug the unused air outlet.
5. Place the sleeve over and around your leg or arm and completely zip up. Position the sleeve so it is comfortable and covers your leg or arm.
6. It is helpful to keep your arm or leg being treated elevated while treatment is taking place.
7. You may sit or lie down as the treatment is being conducted.
8. Check to see that the adjustable pressure control is at the recommended setting.
9. Relax and tum the controller on. A green light will illuminate letting you know that the power is on. It will take several cycles before the recommended treatment pressure is attained.
10. When the recommended treatment time has been completed tum off the controller and disconnect the tubing from the controller to deflate the sleeve.

Suggestions:

Ensure there are no kinks in the tubing

Treatment pressure should never be changed without the direct order of a physician.

Ensure that the zipper is fully secure (zipped completely).

230

Never apply or remove the sleeves while inflated as this may cause damage to the sleeve.

Contraindications for use: The use of the Vaso Press is not recommended in the following conditions-

- In the presence of any pain or numbness
- Severe arteriosclerosis or other ischemic vascular disease
- Massive edema of the legs or arms due to congestive heart failure
- Extreme deformity of the limbs
- Known or suspected deep vein thrombophlebitis

Any local condition in which the sleeves would interfere:

- Gangrene
- Dermatitis
- Untreated or infected wounds
- Recent skin grafts

Recommended Treatment Guidelines

Intermittent Pneumatic Compression (External Pneumatic Compression) is designed to aid in the treatment and management of impaired venous and lymphatic fluid flow. The gentle compression of each cycle enhances the movement of extra cellular fluid from the tissues back in the venous and lymphatic circulation. The extra fluid is then removed by the bodies own natural mechanism.

Following a review of current literature, a recommended treatment protocol has been established. In all cases the recommendations are guidelines and are not a substitute for clinical judgment and experience.

TREATMENT PROTOCOLS

CONDITION	PRESSURE*	DURATION	FREQUENCY
EDEMA			
Dependent	40 mmHg	1-2 hours	twice/day
Traumatic	40 mmHg	30 min. - 1 hour	twice/day
Lymphedema:			
Mild	40-50 mmHg	1-2 hours	twice/day
Moderate-Severe	50-60 mmHg	1-2 hours	2-4 times/day
Venous (post phlebitic syndrome, venous insufficiency)	50 mmHg	30 min- 1 hour	twice/day

Venous Stasis Ulcers	50 mm hg	30 min- 1 hour	twice/day

*When using a gradient compression sleeve set the distal pressure to the recommended pressure setting. There will be an automatic pressure drop once the distal pressure is set.

When using the Vasa Press for wound healing, it is recommended that a clean cotton stockinet be placed over the wound dressings before placing the limb in the Vaso Press Sleeve. Since intermittent compression is an adjunctive therapy it can be used with other prescribed modalities for the treatment of venous ulcers or lymphedema.

Cleaning Instructions

The outside case is made from ABS plastic and should be cleaned using a damp cloth and mild detergent.
Cleaning solutions containing hypocarbonate and phenol bases should never be used as they will cause the plastic to deteriorate.
The sleeve may be washed in luke warm water using a mild detergent.
Care must be taken not to submerge the tubing in water
Do not dry clean
Do not iron
Do not autoclave

Warranty and Service

Britt Medical Products are warranted against defects in materials and workmanship under normal use and operation. Warranties are exclusive and are in lieu of all other warranties (whether written, oral or implied).

PUMP UNITS:

1. The pump will be either repaired or replaced free of charge where defects in materials and/or workmanship are evident at the time of delivery.
2. All labor and parts will be provided free of charge from the date of delivery for a period of 12 months, provided the equipment is returned prepaid to an authorized center.

SLEEVES:
The warranty period for defects in material or workmanship is 3 months

SERVICE: Any product not covered by warranty will be serviced on request. The necessary parts, labor and shipping charges will be billed according to our latest service policy.

Service is available for all Britt products at authorized service centers. Contact our office (732) 863-1400 for service information.

ORDERING INFORMATION

VP 100 Intermittent Compression Pump

SLEEVES FOR THE VASO PRESS CONTROLLER

SINGLE CHAMBER	SEGMENTAL	GRADIENT
VP 101 Half Leg Sleeve	VP 201 Seg. Half Leg Sleeve	VP 301 Gradient Half Leg
VP 102 Full Leg Sleeve	VP 202 Seg. Full Leg Sleeve	VP 302 Gradient Full Leg
VP 120 Full Arm Sleeve	VP 220 Seg. Full Arm Sleeve	VP 320 Gradient Full Arm

*SLEEVE SIZES FOR SINGLE CHAMBER AND SEGMENTAL

				Dimensions					Inserts	
DescriRtion	Single	Segment.	Gradient	L	W	F	H	S	A	B
Half Leg	VP 101	VS 201	VP 301	19.75	23	12.5	-		6	3 5
Full Leg	VP 102	VS 202	VP 302	30	26.5	12.5	-		7	3.5
Full Arm	VP 120	VS 220	VP 320	26			14 5	22 5	5	2

*Other sizes may be ordered on a special order basis. Please call (732) 863-1400 with the dimensions required. Allow three to four weeks for delivery.

SPECFICATIONS

Technical Specifications for the VP 100 Controller

Size: 10 1/4"L , 4 1/2"W, 3 3/4"H
Cycle Time: 3 minutes (90 seconds on, 90 seconds oft)
Pressure Range: 30-80 mmHg
Power: 110-130 Volts, 60 Hz
Weight: 3.5 lb.

233

Appendix D. Preliminary Advertising and Promotional Literature

Appendix D: (Front Page)

Preliminary Catalog Sheet

Vaso Press Intermittent Compression System

(Photograph of the Pump and System in Use)

Versatility in Compression Therapy!

lymphedema or venous ulcers.

One pump for Uniform Compression, Segmental or Gradient Segmental Compression. The Vaso Press from Britt Medical Products Now offers a unique System that will maximize inventory investment and offer flexibility for your patients suffering from .

- One Pump for Uniform, p.tal or- ompression
- Portable, Light Weight, Quiet and Easy to Use
- Promotes Lymphatic and Venous Flow
- Gentle Compression Enhances the Movement of Extracellular Fluid
- Enhances Patient Compliance due to Simplicity and User Friendly Controls
- Promotes Increased Circulation by Simulating Natural Muscle Contractions

BRITT MEDICAL PRODUCTS
45 EAST MAIN STREET-FREEHOLD, NJ 07728

TEL# 732-863-1400 FAX# 732-863-1603

235

(Back Page)

VASO PRESS FROM BRITT MEDICAL PRODUCTS

- Single Pump will operate a uniform or segmented gradient sleeve
- Single Pressure Control for Ease of Operation
- Reduces Swelling and Enhances Wound Healing
- Soft and Pliable Comfortable Compression Sleeves
- Illuminated On/Off Switch
- Safe Non-Invasive Modality

(Close in Shot of the Pump)

(Photographs of Sleeves)

(VP 101)

(VP 202)

(VP 320)

Technical Specifications- Pump
Size: 10 1/4"L, 4 1/2"W, 3 %" H
Cycle Time: 3 min. (90 sec. on/90 sec. off)
Pressure Range: 30-80 mmHg
Power: 110-130 Volts, 60 Hz
Weight: 3.5 lb.

Ordering Information:
VP 100 Intermittent Compression Pump V-
VP 101 Half Leg Sleeve
VP 102 Full Leg Sleeve
VP 120 Full Arm Sleeve
VP 201 Segmental Half Leg Sleeve
VP 202 Segmental Full Leg Sleeve
VP 220 Segmental Full Arm Sleeve
VP 301 Gradient Segmental Half Leg
VP 302 Gradient Segmental Full Leg
VP 320 Gradient Segmental Full Arm

Suggested Use:
Treatment of chronic venous insufficiency, including venous ulcers and edema
Lymphedema, primary and secondary

Contraindications:
Suspected existing deep vein thrombosis
Pulmonary edema from congestive heart failure.
Any local condition in which sleeves would interfere with treatment, such as recent skin graft or gangrene.

(Britt Med. Prod. Logo)

Distributed By:

236

Appendix E. Photographs

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

Appendix F. Performance Testing Data

Protocol for Pressure Measurement

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

[redacted]

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

(b)(4) Commercial Confidential Data / Trade Secret (s) / Proprietary Data

Appendix G. Office of Health Technology Assessment

Health Technology Review

Agency for Health Care Policy and Research | Office of Health Technology Assessment

No. 4 | August 1993

Ly1n1Jl1ede111a Pu111ps: Pneu111atic Con11Jressio11 Devices

S. Steven Hotta, M.O., **Ph.D.** and Thomas V. Holohan. M.D.

Lymphcdema is a swdling of soft tissues. especially in the limbs. dt1L·to the localil.ct.l incrl':tSC in thl' q11;111tity or lymph that results frolll :111 illlpairlllCJll tlr 11JL• lllll"lll;ll Clc;iranCl' by the.: lymphatic sys1cm and/or from <111 cxccssi\'e production or lymph c;1uscd by obstruction of the ve1wus vessels. Pneumatic compression lkviccs \\'crc dc\'elopL d to ;1id in the JllObilization of lymph from lhe extremity. 10 avoid Ille IJH>rhid consl'qUenCl'S or uncontrolled lymphetlcma. These devices have \·aried designs. :111d all ;1ppc;1r 10 he cffcctivc 10 some extent whor1 used in conjunction wi1h an clcntion of 1hL·limh. manual m;issagc. ;111d an cbstic "sleeve" or bant.lagc. This rcviL'\\" L'.\;1111inc.:s dat;1 on the relative effectiveness of single-chambered pneumatic dc:,·iccs vs. 11111ltidl;1111ht:rcd dcviccs. with or without pressurl' c:tlihr:1tions.

Background

P:1t hophysiologically. the n11id accumulating in lymphedem;1 rcprL'Sl'lll an ;1hnorrnal colkction of proteins. w;11a and solute in the interstitial tis...ucs. The st;lg11;1tin11 or this protein-rich lymph m;iy encourage infection <llld result in inllarnm:1111l)' reactions. Fibrosis and cxccssive formation of connective tissues rcprcsent funher scrious consl'quences that m;iy present as elephantiasis or sclcrodermatous changes. The extent to which the

lfc-a/111 frc/1110/o,y lfr1·ir11·s ;in: hrief ev;1Jua1ions or hcahh 1cdrnologics pn:parcd hy 1hc Olfo:c or1-lc.:: 1hh Tcchnolo_;;y Assess111e111. Agency for He;1hh Can: Policy mu Rccarch cOJ IT.V:\11("J>RI or 1hc l'uhlic Hc;1hh .Slrvicc. lc,·ie\\"S m:iy he composed in lieu or a 1cd111ology ;l'.;sc"mcnr bcl";lllSl': 1hc mcdi,al or scilnrilil·IJucs1ions arc li111i1ed and do 1101 w;1rr 1111 lhe rlSt>tirccs 1"<:411ired "" ;1 full assco;111cnl: 1hc a\"ai1:1hlc l!\·id. ncc is li111il.:d ind 1hc p11blishcd mcdie;1J or scicnlilic li1.:ra1urc is insulfo.:icn1 in qu;1li1y or lJU:11>lily for an u .:ss111c111: or the li111c f.·;m1.: av;1i1:1blc pr.:cludcs u1iliz;11i11n of 1hc 1°1111. fon11al ;l'·t·'111;111 pro.:css. This rcpon has hcen prcparcd in response ro a rClJUCSI from lhc Health Care Fi11;111,in;: \d111ini,1ra1j,>11 (HCF,\).

215

swelling has progn:ssed toward thcs.: btter st:1ges inlluenccs the effectiveness of the tre:1tment of patients with lymphedema. For example, Jymphcdenm following radic<tl mastectomy <ind/or r<1diation ther:1py may respond rc:idily to the appli<::1tion of external pressu res. when:as the response to the same treatment may he limited if the condition has progressed to the stage of fibrotic changes. Fu nhermorc, the treat:1bility of the lymphedema may also depend on the etiology of the condition- that is. whether the J ympheuema. is the result of a congenital absence of ·or abnormalities in the lymphatic system or is secondary to an identifiable c:1use such as tr:n11na. surgery. radiation therapy. infection. or malignancy.

Early treatment for Jymphedema consisted of the elevation of the limh and manu:tl massage to encour:1ge dr:iinage of lymph from the limbs. El 1stie bandages and sleeves aided drainage and were somewhat effective in preventing the accumulation of lymph.[1-3] Among the early compression devices used to facilitate the mobilization of lluid from the limbs was one type that consisted of a single inflatable chamber that :1pplicd relatively uniform pressure to the whole limb. The development of mullichambered devices allowed the sequential application of pressure from the distal to proximal direction. This "milking" of the extremity was thought to be more effective in removing the lymph from the cxtn:mity. The latest modification to these pneumatic compression devices w:1s the incorporation of a control mechanism to permit the delivery of calibrated pressure gradients with a multichambered device.

All pneumatic compression devices appear to be effective in patients with treatable lymphedema, the magnitude of such effects depending in part on the tissue changes that may hinder the drainage of lymph and thus the reduction of the swelling. The successful treatment of patients with lymphedema may require the use of elastic bandages or sleeves between treatments with these devices.

Published Literature ,,,.,,,.,,,. ,,,.

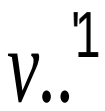
A computer search of the Medline data base (J 966- 1992) found 38 references that were relevant to the treatment of lymphedema with lymphedema pumps or pneumatic compression devices. Nine of these references presented data on the effects of the varous pumps in the treatment of series of p:1tien1s, each study including patients with lymphedema or varied etiology (Table I). One study compared the effects of three different treatment modes: manual m:1ssage. singk-chambered device. <ind multicharnbercd (uncalibrnted) compression device. Seven of the nine refcrcnces reported data showing the extent of reduction in the volume of excess edema lluid (Jiffcrencc in measurements between the edematous limb and the normal, control limb) with trcntment. and the remaining two reported volume or 11)easurement changes with treatment only in the edematous extremity. The selection criteria for putients to be treated varied from study to study. and even within a study the characteristics of the Jymphedema were not defined, so the treatability of the Jymphedema may have varied from patient to patient. With two exceptions, the studies reponed data only on the effect of a single, short-tenn application of the device on the reduction of lymphedma.

Z:rnolla et al.i compared three different protocols for treating Jymphedema in 60 patients who had had radical mastectomies. Each group consisted of 20 women. Group I received intermittent pressure treatment with a single-chambered compression device for 6 hours per day for I week. Group 2 was treated with cyclical sequential pressure application via a multichambered device for 6 hours per day for I week. Group 3 received manual massage for l hour 3 days per week for I month. After the treatments, all patients wore elastic sleeves during the day and were given 60 mg of benzopyrone (purported macrophage activator) every day. The difference between the circumference of the edematous arm at the maximum edema point and that of the nonnal arm was determined before therapy,

Table 1. Treatment of lymphedema

Reference	N	Etiology (N)	Device	Protocol	Reduction of lymphedema
Zanolla [4] (1984)	20	Mastectomy	None	Manual massage, 1 h 3/d/wk for I mo	18%
	20	Mastectomy	I-Chamber	6 *hid* x 7	21%
	20	Mastectomy	Mulli-chamber	6 h/d x 7	21%
Swcdborg[5] (1984)	54	Mastectomy	I-Chamber	6 h/d x 2 wk	17.7%
BcneJJi[6] (199I)	6S	Mastectomy	I-Chamber	(i h/d 2 mo 6 mo	 16.5% 18.9%
Raines[7] (1977)	17	Mastectomy Hysterectomy Radiation Sepsis	I-Chambcr	*24* h (alternate 4h on md 30 min off)	25% (1 1 arms) 45% (6 legs)
Richmand [8] (1985)	24 (16F. SM)	Primaz (9) Secon ary Radiation Malignancy Infection Mastectomy	Muhi-chamber	lntermiuent sequential pressure for 24 h	25-45%(7 arms) 36-47% (18 legs)
Zcl ikovski[9] (1985)	20 (17F, JM)	Mastectomy Idiopathic	Multi-ch;ui1bcr	:'i-6 h/d x 2	21 .8%
Yamazaki III (1988)	26	Mastectomy	Multi-chambcr	40-60 min/d or every other d;iy for l:'i mo	14/26: Sicnific<int reauct ion 7/26: no ch;inge 5/26: worsen
s? ingl l	15	Mastectomy	Multi-chamber with cal ibrated pressure gradient	38 h. 48 h tre<itment protocol	49.4%
Klein [1:!] (1988)	73 ficant (56F, decrease 17M)	ldiopath ic(30) Congenital (8) Trau ma (I) Pregnancy(2) Misc (2)	Multi-Surgery(25) -calibrated pressure gr:idient	38 h. 48 h chamber with protocol	Sign i treat ment in circumference of edematous limbs

at the end of the therapy, and 3 months after therapy. Patients in all protocols showed significant reductions in lymphedema immediately after therapy, with little difference in the effectiveness of the three modes of therapy. The average reduction in the difference between the edematous and control limbs immediately after conclusion of the therapy was 21% in the women treated with the single-chambered device (group I). 2I% in the women treated with the sequential compression device (group 2). and I8% in the women treated by manual massage (group 3). Measurements taken



I month •lh:r 1hi.: ccssalion of lhc thi.:rapy si.:ssions showed that the edema fluid appeared to have n;accumulated only in the women trcatc<.I with the si.:qucntial compression <.levicc (percenl reouctions of the lymphedcma were 21%. 5%. and 2Yk at 3 monlhs in groups I.2, and 3. respect ively).

Supporting evidcnci.: for the effi:ctivcncss of a sin!.!le-chamhi:rcd compression di:vici.: was ohi.:rvi.:d !!1 other studies. Swcdhnrg.5 round that the applic:llion or this device for 6 hours cvi.:ry day for 2 weeks (2 days off in the middk) rcdul'l:d the lymphi:dcma hy :in average of I7.7'kin 5-J post111:1stL·ctomy patients. lkrh;lli ct al" treated M pos1111as1cctorny paiclllls with lyrnphi:di rna for 6 hours every lby and found that thi: cdi:rna was n.:duccd. on the :1veragc. hy aho111 I*6.S'b* at 2 months and ahoul IX.9'k al 6 months. Individual responses varied greatly such that ahoul one half or the patients showcd ri:dm:tions of cdi:ma grc:1tcr than 25%. ahout 5% had a worseni ng or edema. and the remainder had a reduction of less th;in *25'J11.* In a study of 17 patients with Jymphedema of v;irious etiologies, Rai nes ct al[7] found that intermittent pncu1m11ic compression trc:11mcnt for a 24-hour period resulted in the reduct ion of lymphcdcma hy ahoul *25'7r* in the arms of 11 patients and hy ahmll *45'ii-* in the legs of 6 patients.

Thi: t rca1mcn1 of lymphedema by the applic:11ion of pressu re sequent ially from th.: distal to proxi mal direction with a multichambered device. without calibrated pressu re gradients. also showed similar \'aricd ri:sults. Rich mancl ct als trearcd 24 lymphcdcma patients (16 rcnwh:s <llld 8 males) with intcnnittent sequent ial pressure application for 24 hours and found that the treat ment reduced the edema by 25%-45% in rhe si:vcn upper limbs and by 36<k-...J7% i11the 18 lower limbs. Zelikovski cl aJ[9] reported that the 1n:atme11t of 20 p;11ie11ts over :1 2-day period result ed in in :1vcrage ri:tl uction in edema of 21.8%, but observed that the indi vi<.l ual responses varied from 0%-63%. Ya mazaki el al[10] applied sequent ial pressure for 40-60 min utes every day or every ot her day to the edematous arm of 26 post masiectomy patien ts. They reported that 14 of the p:.nien ts showed a si_: nificanl reduction in lymphcdcm;1 after 15 months of 1re:11ment. 7 showed no change. and 5 continued to ;1c.:c.:unrnl:uc edema fluid.

A Jllulticharnhcred device with a c.:alihr;111:d pressure gradient was used by Kirn-Sin!! and Basco[11] and Klein ct al.[12] Kim-Sing ind Basrn[11] reported that the tri::11rncnt of 15 post rnastcc10111y patients with intcrmit1ent t:al ibra ted pressu re gradient applicaliPll i"or 48 hours resulted in the rcduc.:1ion or lymphcdcma hy an average of 49.4%. with individual responses varying from 1 3%-68.7'/(,. Klein ct :11[1]:? tn:ati:d 73 patients with l ower ext remity l y mphcdcma si mi larly for 48 hours and reported only the c.:hangi:s in cirrn m ferenc.:cs 01:1he treated limbs before and :d"ti:r the treat ment. Although Klein ct alt2 noted that these reductions in c.:in.:umkn;nces at live levels of the treated limh wi:ri: signific:111t. comparati vi: measurements of the norrn:d. control ex1rcmity were not m:idc, thus cakulation of the absolute reduction of lymphcdcma w;is not possible.

Discussion

The treatment of lymphcdema by the application of external pressu re to tht! ext remity by manual massage, elast ic sleeve or wrnpping.[13•1]_, immersion in liquid tanks.[15] or pneumat ic compression devices appi:ars lo bi: relat ively effcc1ive. Whether any mo<le of pressure application is mori: or less effective in pushing 1hc lymph out of the limb probably is dependent on a number of factors. including whether lymphatic channels or the venous vessels arc obstructed. Thus manual massage with elevation of the limb and use of elastic sleeves or wrappi ngs may suffice to control the lymphedema in mild or early cases. while more severe or longs1anding lymphedcma may benefit from the use of external pressu re devices.

According to the .studies reported in the literat ure, all modes of external pressure application effectively reduce lymphcdema in most p:uients. Since none of the studies specified uniform criteria for the selection of patients or the ch<.irac1eris1ics of the lymphedema, comparison of the relative

effectiveness of the various modes of external pressure therapies cannot be meaningfully done. Even in the case of postmastectomy patients, who may represent the most treaiable group of patients, no artempt to define or control for uniformity in the severity, duration, or complexity (e.g.. fibrotie changes) of the lymphedema among the patients was evident. In view of these uncenainties, one can only conclude from the data in the li1cra1urc th:ll manual massage, pressure applied with a single-chambered pneumatic device. and sequential pressure applied with a multichambered device, with or without a calibrated pressure gradient. all ;.ire effcctivc to some degree in ri.:ducing lymphedcma i1.i some patients.

Muhichambcred devices which were developed for the intermittent application of pressure sequenti:illy from the distal to proximal direction in an attempt to effect rhe mobilization of the lymph by a "milking" action, may be more effective than single-chambered devices in selected patients. However, which patients these are cannot be determined from the published information. The published studies have only demonstrated that the reductions of lymphedcma i;1 some p;itients treatd with the multichambercd devices appear to be similar to those obt;iined with the use of a single-chambered device and with manual m;issagc.

A multichambered device \vith a mechanism to apply :1 calibrated pressure gradient that automatically adjusts the pressures to limb conditions was developed with the hope that this controlled pressure application would be more effective in the mobilization of the lymph. From the two studies that reported the rcsuhs of usin!! this device in patients. the advantages of - applying ealibratcd pressure gradients are not apparent. Allhough the patients treated by Kim-Sing and Basco[11] appeared to have a grea1er average reduc1ion in lymphedema, the responses appear to be comparable with those observed with the use of other modes of therapy. The number of patients in their study was small and the individual responses of their patients varied over • wide range, which was similar to that reponcd for other modes of therapy. In the other study.[12] the reponed results indica1ed that the device decreased the circumferences of the treated limbs, but the significance of these changes arc unknown because the au1hors did no1 rcpon comparative measuren11.:nts of the normal limbs.

The selcction t)f patic111s who had faikJ : to respond to one or ano1her mode or therapy and the finding 1hat some of these paticms responded to the treatment under study would suggest that whether the lymphcdema might be successfully treated hy one or another mode of therapy m:1y depend on the individu;1l patient. It is conceiY;1blc 1hat musr 11ncomplic:.11cd lympheJcma could be treated sa1isfac1orily by any of 1he extcrn;il pressuri.: modes of therapy. while others may ri.:spond more favorably to one or another therapy. Lymphcdcma difficult to control by one mode of therapy may benefit by the use of another. Da1a that might be u.seful for the selection of the best candidates for treatment by a given mode of therapy arc lacking at this time. TI1cse studies did not address important questions concerning the effccti,eness of these pncumati<.: compression devit:"cs t)\'er the long-1enn and the most appropria1c frequent:"y and duration of use of lhcsi.: Jcvices.

Pneum;11ic compression pumps were appro\·ed for marketing by the Food and Drug Adminis1ration (FDA) as devices ihat were suhstan1ially equivalent to similar devices marketed prior 10 the 1976 Medical Devices Amendments to the Federal Food, Drug anJ Cosmetic Act. The possible · uniqueness or superiority of one pump vs. anolher was not a consiJer:1tion for 1hesc appro,als by the FDA. TI1e National lnstitult'S of He:1lth has agreed wi1h our findings that. ahhough these pneum:itic compression devices appear to be useful in !he treatment or lymphcdema. there is a lack of data to determine whether one device is more eflicacious than another or to ascenain the best protocol for their use.

Patiems have been reimbursed for the purchase md use of these pneumatic cornpr<?ssion dcvi<.:es. The avcra!.!c allowed charge for pun.:hase by i\kdicar in 199 I were S198.15 for singk-d1arn bcrcd

lymphedema pumps. $535.01 for multichambered devices, and $1,437.39 for multichambered devices with calibrated pressure gradients. In 1991, Medicare patients purchased 8.299 single-chambered devices at a total cost of $1,644,448; 1,329 multichambered devices at a lotal cost of $711,030; und 9,989 multichambered devices with calibrated pressure grndicnts at a total cost of $14,358;0)4.

Summary

Lymphcdema is the abnormal accumulation of lymph in the interstitial tissues that is usu:illy the result of impairment of the normal clearance by the lymphatic system caused by therapy or disease. The application of external pressure represents a reasonable and successful method for the mobilization of lymph from the :1ffected limb in some patients. Pneumatic compression devices consisting of a single inflatable chamber or multiple chambers have been developed and used in the successful reduction of lymph_edema. Multichambered devices allow the application of pressure sequeniially, sturting from the dist:il chamber and progressing proximally, theoretically encouragi ng an effective, unidirectional flow of lymph out of the limb.

All pneumatic compression devices appear to be similarly effective in the treatment of lymphedema. Since the patients selected varied from study to study and the characteristics of the lymphedema among the patients were not defined, neither the criteria for the selection of patients to be treated with one or another device nor the difference in effectiveness of the devices could be ascertained.

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August 1993

Appendix H. UL Listing Document

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Our Reference:

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Appendix I. Truthful and Accurate Statement

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required By 21 CFR 807.87(j))

I certify that, in my capacity as PRESIDENT of BRITT :MEDICAL PRODUCTS, I believe to the best of my knowledge, that all data and information submitted in the Premarket notification are truthful and accurate and that no material fact has been omitted.

Signed:
Name: J. James Britton
Position: ent
Date: November 18, 1997

254

Appendix J. 510 (k) Statement

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Name: J. James Britton
Address: Britt Medical Products
PO Box 547
45 East Main Street, Suite 204
Freehold, NJ 07728

Contact Person: J. James Britton
Phone Number: (732) 863-1400
Fax Number: (732) 863-1603

This statement regarding 51O(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.93.

I certify that in my capacity as PRESIDENT OF BRITT MEDICAL PRODUCTS I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Signed:

Name: J. James Britton

Position: President

BRITT CORP

P.O. Box 547 • 45 E. Main St. Suite 204 • Freehold, NJ 07728
Phone (908) 863 • 1400 Fax (908) 863 • 1603

November 18, 1997

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Attn. Document Control Clerk
Re: 51O(k) PREMARKET NOTIFICATION

Pursuant to section 510(k) of the Federal Food, Drug, and Cosmetic Act, premarket notification information is enclosed for the following device:

Device Name: Intermittent Compression System
Trade Name: Vaso Press System
Common Name: Intermittent Compression Unit and Compressible Limb Sleeve
Classification Name: 870.5800 Compressible Limb Sleeve
Device Class: Class II
Classification Panel: Cardiovascular
Performance Standards: There are no performance standards for this system.
Facility Address & Establishment Registration Number:
Britt Medical Products a Division of Britt Corp.
45 East Main Street, Suite 204
Freehold, NJ 07728
Registration Number: (b)(4) Commercial Confidential Data /
Reason For Submission: The Vaso Press System is a new device for Britt Medical Products but similar in form, function and design to existing products currently marketed by several companies.
Contact Information:
Name: J. James Britton
Address: Britt Medical Products
45 East Main Street, Suite 204
Freehold, NJ 07728
Telephone: (732) 863-1400
Fax: (732) 863-1603

Should additional information be required, please contact me immediately.

Sincerely,

J. James Britton
President

FDA/ CDRH IMAGING SYSTEM

Page Count Discrepancy Information

Page after page 170 is misnumbered.

Verifiers Initials _____...