FEB - 1 2005

120 W. Commercial Avenue, Moonachie, NJ 07074 _ 201-939-0716 _ 800-888-0908 _ Fax: 201-939-4503

510(k) Summary
Model SC-3008 Sequential Circulator
510(k) Number K043423

Submitted in accordance with the requirements of SMDA 1990 and 21CFR807.92.

1. APPLICANT'S INFORMATION:
   Ron Motherwell
   Executive Vice President
   PH: **201** 939-0716
   FX: **201** 939-4503
   Internet: http://www.biocompression.com
   Medical Establishment
   Registration No.: 2424387

2. SUBMITTER'S INFORMATION
   James Jochen Rogers
   General Manager
   Coastal Consulting Group, Ltd.
   P.O. Box 470218
   Broadview Heights, OH 44141
   PH/FX: **440** 546.4936
   Mobile: **724** 7.13.2298
   E-mail: coastalcg@earthlink.net
   Internet: http://www.coastalcg.com

3. Date: November 27, 2004

4. DEVICE INFORMATION
   DEVICE NAME: Model SC-3008 Sequential Circulator
   Classification Panel: Cardiovascular and Respiratory Devices
   Classification Number: 870.5800
   Product Nomenclature: Compressible Limb Sleeve
   Product Code(s): JOW
   Trade/Proprietary Name: Model SC-3008 Sequential Circulator
   Common Name: Model SC-3008 Sequential Circulator

5. DEVICE CLASSIFICATION:
   Compressible Limb Sleeve Devices are classified as Class II devices, and reviewed by the Division of Cardiovascular Devices.

6. PREDICATE DEVICE(s):
   - K810338 Lymphapress
   - (Pre-amendments) The Sequential Circulator

7. DEVICE DESCRIPTION:

The device consists of a manual pump (e.g., the user manually adjusts the pressures, while the inflate/deflate cycle times remain constant) and a sleeve or garment containing discrete, segmented inflatable chambers externally applied over the affected extremity. The pump consists of a compressor capable of a maximum pressure of 150mmHg, and provides graduated, or gradient, pressurization to the chambers (e.g., sequential inflation of distal to proximal, with distal chambers inflated to a greater pressure than the proximal ones). . A calibrated dial gauge displays pressure in the range of 0-125mmHg.

As each chamber is inflated, the pressure is held constant until all chambers are inflated, in order to prevent reverse gradient flow. Once all chambers are inflated, they are then all released simultaneously, and the cycle repeats. Pressures within the chambers are adjustable - pressure to chambers 1&2 is controlled by a user-adjusted regulator on the pump. Pressure in chambers 3&4, 5&6, and 7&8 can be individually lowered from the default factory settings.

Garments are available in 10 sizes, and custom garments are available in variations from these standard sizes; an adapter is available to support bilateral treatment:

Arm – Small	Leg – Small	Leg – Adjustable Small
Arm – Medium	Leg – Medium	Leg – Adjustable Medium
Arm – Large	Leg – Large	Leg – Adjustable Large
Arm – w/ Shoulder	Arm – Custom	Leg – Custom

8. INDICATIONS FOR USE:

The Model SC-3008 Sequential Circulator is a manual, sequential, pneumatic compression device intended for the primary or adjunctive \ treatment of primary or secondary lymphedema. The device is also intended for the additional or alternate treatment of venous insufficiency, and chronic venous stasis ulcers associated with venous insufficiency, as well as general treatment of swelling of the extremities. The device is intended for home or hospital use.

9. TECHNOLOGICAL CHARACTERISTICS:

The manufacturer believes that the technological characteristics of the Model SC-3008 Sequential Circulator are substantially similar to those of the predicate devices.

10. PERFORMANCE DATA:

Performance testing was performed and assures that the product meets its specifications.

11. STATEMENT OF SUBSTANTIAL EQUIVALENCE:

Based upon safety and performance testing, compliance with voluntary standards, and comparison to the predicate devices, the manufacturer believes that the Model SC-3008 Sequential Circulator is substantially equivalent to the predicate devices, and does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Bio Compression Systems, Inc.
c/o Ned Devine
Entela, Inc.
3033 Madison Avenue, SE
Grand Rapids, MI 49548

Re: K043423
Model SC-3008 Sequential Circulator
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: December 10, 2004
Received: December 13, 2004

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Donna R. Bucher

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

Enclosure

510(k) Number (if known): K043423

Device Name: Model SC-3008 Sequential Circulator

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(21 CFR801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Wichmer

(Division Sign-Off)
Division of Cardiovascular Devices

(510(k) Number K043423