K 122112

II. 510(k) Summary

APR 09 2013

APPLICANT'S INFORMATION

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SUBMITTER'S INFORMATION

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DATE PREPARED: March 29, 2013

DEVICE INFORMATION

DEVICE NAME:	2008-OC and 2004-OC Massage Systems
Classification Panel:	Surgical, Orthopedic and Restorative Devices
Classification Number:	890.5650
Product Nomenclature:	Powered Inflatable Tube Massager
Product Code(s):	IRP
Trade/Proprietary Name:	2008-OC Massage System
	2004-OC Massage System
Common Name:	2008-OC Massage System
	2004-OC Massage System

DEVICE CLASSIFICATION

Powered Inflatable Tube Massager Devices are classified as Class II devices, and reviewed by the Division of Surgical, Orthopedic and Restorative Devices.

PREDICATE DEVICE

DJS Massager (K112479; product code IRP) manufactured by Mego Afec AC LTD.

DEVICE DESCRIPTION

The device consists of an air compressor with manually adjustable pressure settings (i.e., the user manually adjusts the pressure, while the inflate/deflate cycle times remain constant) and a sleeve or garment containing four (2004-OC) or eight (2008-OC) discrete, segmented inflatable chambers externally applied to the limb.

The pump consists of a compressor capable of a maximum pressure of 150 mmHg, 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).

An in-line check valve limits the output pressure to 80 mmHg, and a calibrated dial gauge displays pressure in the range of 0-125 mmHg.

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 distal chambers have a default value set at the factory (60 mmHg distal), and can be adjusted by the user to distal pressures between 30 mmHg and 80 mmHg. Pressures decrease by 5 mmHg in each proximally sequential chamber.

Garments are available in sizes to accommodate varying limb lengths. An adapter is available to support bilateral treatment.

INDICATIONS FOR USE

The Model 2004-OC and 2008-OC Massage Systems are powered inflatable tube massagers intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas. The device is intended for home use by people who are in good health.

TECHNOLOGICAL CHARACTERISTICS

The manufacturer believes that the technological characteristics of the 2004-OC and 2008-OC Massage Systems are substantially similar to those of the predicate device.

PERFORMANCE DATA

Before being released, every device is tested and must meet all performance specifications. In addition to aesthetic acceptance criteria, functional testing includes electrical leakage, inflation pressure in each segment, pressure adjustment, pressure gradient across the segments, air pressure gauge accuracy, and inflation/deflation cycle times.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

The Bio Compression Systems Model 2004-OC and 2008-OC Massage Systems and the predicate device all provide sequential inflation pressure from distal to proximal segments. Both the Bio Compression and predicate devices offer adjustable pressure ranges.

The Bio Compression devices have decreasing gradient pressures from distal to proximal segments, which prevent flow of lymph back into the limb, while predicate device does not have decreasing gradient pressures. The Bio Compression devices provide continuously adjustable pressure in the range between 30 to 80 mmHg, while the predicate device provides three pressure adjustments options in increments of low, medium and high pressure ranges within the 20 to 80 mmHg range. The Bio Compression devices have fixed cycle times that are fixed by a motorized valve, and are independent of garment size and number (one or two garments). The predicate device does not have a motorized valve and uses back pressure to trigger the cycle to the next chamber of the garment.

Both the Bio Compression devices and the applicant device operate within clinically-established parameters. The differences between the predicate and the applicant devices do not impact safety or effectiveness. A table illustrating the similarities and differences is provided below.

Similarities and Differences with the Predicate Device

Parameter	2004-OC	2008-OC	K112479 DJS Massager
Intended Use	Temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas. The devices are intended for home use by people who are in good health.		
Principal of Operation	Sequential pneumatic compression	Same	Same
Weight	8 pounds	8 pounds	5.1 pounds
Dimensions, inches	5.5H X 8 L X 12 W	5.5H X 8 L X 12 W	3.9 H X 10.2 L X 5.1 W
# of Segments in garment	4	8	4
Sequential segment inflation	Yes	Yes	Yes
Distal to Proximal gradient	Yes	Yes	No
Inflation Time, each segment	18 seconds	5.5 seconds	Approx. 10 (one garment) or 18 (two garments) seconds
Inflation Pressure	30 - 80 mmHg distal, adjustable in 1 mmHg increments	30 - 80 mmHg distal, adjustable in 1 mmHg increments	20 - 80 mmHg, adjustable in 3 ranges: 20-30, 40-60 and 70-80
Locking pressure adjustment knob	Yes	Yes	Yes
Pressure Gauge	Yes, 0 - 125 mmHg	Yes, 0 - 125 mmHg	No
Deflation Time	18 seconds	5.5 seconds	Approx. 10 (one garment) or 18 (two garments) seconds
Pause time between inflation cycles	None (deflation time is pause time)	None (deflation time is pause time)	Adjustable in 3 levels: 10-20, 30-50 and 60-70 seconds
Total Cycle Time	90 seconds, fixed (one or two garments).	50 seconds, fixed (one or two garments)	Variable: Approx. 50 (one garment) or 90 seconds (two garments)
Garments Available	Sized leg and arm/shoulder	Same	Same
Fail-safe hose connectors	Yes	Yes	Yes
Bilateral Treatment Option	Yes	Yes	Yes
Power Requirements	115VAC, 50-60Hz	Same	Same

Based upon safety and performance testing, compliance with voluntary standards, and comparison to the predicate devices, the manufacturer believes that the 2004-OC and 2008-OC Massage Systems are substantially equivalent to the predicate device, and do not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 9, 2013

Bio Compression Systems, Inc.
c/o Ms. Maureen N. Garner
President
1983 Hazelwood Road
Toms River, NJ 08754

Re: K122112/S001
Trade/Device Name: 2004-OC Massage System, 2008-OC Massage System
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: April 1, 2013
Received: April 2, 2013

Dear Ms. Garner:

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122112

Device Name: 2004-0C Massage System, 2008-0C Massage System

Indications For Use:

The 2004-0C and 2008-0C Massage Systems are powered inflatable tube massagers intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas. The devices are intended for home use by people who are in good health.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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