k122480/5001

Attachment I

MAR 2 7 2013

510(k) Summary
International Biophysics Corporation HFCWO Vibratory Vest

This 510(k) Summary of Safety and Effectiveness for the IBC HFCWO Vibratory Vest is submitted in accordance with the requirements of SMDA 1990 and following guidance concerning the organization and content of a 510(k) summary.

Applicant:	International Biophysics Corporation
Address:	2101 E. St. Elmo Road, Suite 275 Austin, Texas 78744
Contact Person:	H. David Shockley, Jr., CEO & President
Telephone: Fax: Email:	(512) 326-3244 (512) 326-3299 hdavid@ibcbio.com
Preparation Date:	July 15, 2012
Device Trade Name:	International Biophysics Corporation AffloVest
Common Name:	IBC HFCWO Vibratory Vest
Classification Name:	Therapeutic Device, Powered Percussor 73-BYI 21 CFR 868.5665
Legally Marketed Predicate Device	K965192 – Hill-Rom The Vest® Airway Clearance System by Hill-Rom is manufactured by Hill-Rom at 1020 West County Road F, St. Paul, MN 55126. The vest is intended to use HFCWO to dislodge mucus from the bronchial walls, increase mobilization, and move it along toward central airways. The action also works to thin thick secretions, making them easier to clear. Once the mucus has moved from the

	smaller to larger airways, it can be easily removed by coughing or suctioning. K053248 – Electromed Inc. The SmartVest®' Airway Clearance System, Model TL is designed to deliver high-frequency chest wall oscillation to promote airway clearance and improve bronchial drainage. The SmartVest® System is indicated when external chest manipulation is the physician's treatment of choice to enhance mucus transport.
Description of the Device	The International Biophysics Corporation HFCWO Vibratory Vest is comprised of a vest of synthetic polymer fabric with installed oscillating vibratory motors organized into six zones. It has three buckles and straps on the front and one over each shoulder that are used to provide the wearer with a snug and evenly-distributed fit. Additionally, there is an included charger for the batteries and a remote that is wired into the vest to adjust the intensity of the oscillation on the patient as necessary and as prescribed by a physician.
Intended Use of the Device	The International Biophysics Corporation AffloVest is intended for promoting airway clearance and improvement of bronchial drainage by enhancing mobilization of bronchial secretions where external manipulation of the thorax is the physician's choice of treatment.
Nonclinical Performance Data:	None required
Clinical Performance Data:	None required
Conclusion:	The International Biophysics Corporation AffloVest is substantially equivalent to other existing legally marketed HFCWO vests that are currently in commercial distribution.
Additional Information:	None requested at this time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 27, 2013

Mr. H. David Shockley, Jr.
Chief Executive Officer & President
International Biophysics Corporation
2101 East Elmo Road, Suite 275
AUSTIN TX 78744

Re: K122480
Trade/Device Name: International Biophysics Corporation HFCWO Vibratory Vest
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: II
Product Code: BYI
Dated: February 19, 2013
Received: February 1, 2013

Dear Mr. Shockley:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: K122480

Device Name: International Biophysics Corporation HFCWO Vibratory Vest

Indications for Use:

The International Biophysics Corporation AffloVest is intended for promoting airway clearance and improvement of bronchial drainage by enhancing mobilization of bronchial secretions where external manipulation of the thorax is the physician's choice of treatment.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use_____(per 21 CFR 801.109)

Lester W. Schultheis Jr

Digitally signed by Lester W. Schultheis Jr
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300188833, cn=Lester W. Schultheis Jr
Date: 2013.03.26 14:00:36 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122480