510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: k121661_.

DEC 27 2012

1. Submitter's Identification:

Mr. Peter Glassberg
Assist Fill, LLC
7143 NW 67 Way
Parkland, FL 33067
Tel: 954-232-8676

Date Summary Prepared: December 17, 2012

2. Name of the Device: EZ-ASSIST-FILL

3. Common or Usual Name: Daily Activity Assist Device
Classification: 21 CFR 890.5050 product code: PCM

4. Predicate Device Information:
Puritan-Bennett Helios Universal, cleared under K993220
Fred Sammons Inc. Jar Holder & Opener cleared under K813631

5. Device Description:

EZ-ASSIST-FILL is designed to support any combination of portable and reservoir units that use downward pressure to effect the transfer connection. EZ-ASSIST-FILL consists of a telescoping spring arm assembly mounted on a fiberglass base plate using pivot which allows the spring arm to rotate through 90 degrees to swing over the portable unit when in refill position. The entire unit is held in place by the weight of the reservoir, which rests entirely on the base plate. There is no need to remove the reservoir from EZ-ASSIST-FILL between uses.

6. Intended Use:

EZ-ASSIST-FILL is intended to assist the user with refilling a portable liquid oxygen tank. The device is for use in homes or clinics.

The EZ-ASSIST-FILL is neither a life-sustaining, nor life-supporting device. The device is intended for Over-the–Counter use.

7. Technological Comparison to Predicate Devices:

The device performs the same function as a person applying pressure during filling. The only difference is that the assist device arm needs to be moved into position to hold the oxygen unit in place during filling.

The EZ-ASSIST-FILL is designed with similar intent as Fred Sammons Inc. Jar Holder & Opener that being to hold an object in place replacing the required user physical strength to achieve the same end results without using the assist device.

The predicate is mounted to a flat, stationary workspace in order to provide assistance holding the jar in place while the person opens a jar, while the subject device is mounted on to the reservoir tank to provide assistance holding the lever in place while the user fills the tank.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Bench testing was performed to assess functionality of the EZ-ASSIST-FILL. The EZ-ASSIST-FILL devices were tested according to the "EZ-ASSIST-FILL Production Unit Repeatability Test". The devices met the requirements of the predetermined acceptance criteria, which confirmed that the EZ-ASSIST-FILL held the portable oxygen tank in place without any manual intervention and the portable tank was successfully filled when using the EZ-ASSIST-FILL. All devices passed the test.

9. Discussion of Clinical Tests Performed:

Clinical testing was not performed.

10. Conclusions:

Based on the information provided in this submission we conclude that the EZ-ASSIST-FILL is substantially equivalent to the predicates and is safe and effective for its intended use.

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

December 27, 2012

Assist Fill, Limited Liability Company
C/O Ms. Maria F. Griffin
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
GREAT NECK NY 11021

Re: K121661
Trade/Device Name: EZ-Assist-Fill
Regulation Number: 21 CFR 890.5050
Regulation Name: Daily Activity Assist Device
Regulatory Class: I
Product Code: PCM
Dated: December 17, 2012
Received: December 20, 2012

Dear Ms. Griffin:

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,

Kwame O. Ulmer

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

Attachment 1

Indications for Use

510(k) Number (if known): k121661

Device Name EZ-ASSIST-FILL

Indications For Use:

EZ-ASSIST-FILL is intended to assist the user with refilling the portable liquid oxygen tank. The device is for use in homes or clinics.

The EZ-ASSIST-FILL is neither a life-sustaining, nor life-supporting device. The device is intended for Over-the–Counter use.

Prescription Use _____ **OR** **Over-The Counter Use** X
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nayan J. Patel -S
2012.12.27 12:10:33 -05'00' For Lex Schultheis

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

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