K033518

MAR 1 0 2004

510(k) Summary
(As required by 21 CFR 807.92(a))

A. Submitter Information

Custom Plastic Products, Inc.
4519 Hastings Court
Chino, CA 91710

Phone Number: 949-364-9349
Fax Number: 949-347-1204

Contact: Jim Barley
Regulatory Affairs
Date: October 24, 2003

B. Device Information

Trade/Proprietary Name: Lotus Pulmonary Function Filter

Common name of device: Pulmonary Function Filter

Classification Name: Filter, Bacterial, Breathing-Circuit

C: Predicate Device: Creative Biomedics, Inc.
Clear Advantage Pulmonary Function Filter

Predicate 510(k) #: K951410

D. Device Description:

The Custom Plastic Products Pulmonary Function Filter is a disposable barrier type filter intended to prevent contamination cross-contamination when using spirometers and pulmonary function testing instruments. The filter also prevents the transmission of harmful bacteria from the instruments to the patient.

The device consists of a plastic housing with a filtering efficiency greater than 99%. The filter is designed for inspiratory and expiratory air flow.

E. Intended Use:

The Custom Plastic Products Pulmonary Function Filter is intended to prevent cross-contamination between the patient and the spirometers and pulmonary function testing instruments.

F. Comparison of Required Technological Characteristics:

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the Custom Plastic Products Lotus Filter and the cited predicate device.

G. Summary and Conclusion of Nonclinical and Clinical Tests:

Prior to testing, First Article Inspections were conducted on all components. In addition, material verification was performed on all components.

Cytotoxicity and Bacterial Filtration Efficiency Testing were performed on the device's filter.

To shown that test results using the Lotus Filter were accurate, Standard Force Vital Capacity Tests were performed using both the Lotus Filter and the predicate device. The results of testing showed that test results using the Lotus Filter were substantially equivalent to the Creative Biomedics Inc. Clear Advantage Filter.

Conclusion:

The Custom Plastic Products Lotus Filter is substantially equivalent to the Creative Biomedics Inc. Clear Advantage Filter in indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2004

Mr. Jim Barley
President, JB and Associates
28481 La Falda
Laguna Niguel, CA 92677

Re: K033518
Trade/Device Name: Lotus Pulmonary Function Filter
Regulation Number: 21 CFR 868.1840
Regulation Name: Spirometer, Diagnostic (Accessory to)
Regulatory Class: II
Product Code: BZG
Dated: February 23, 2004
Received: February 24, 2004

Dear Mr. Barley:

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. 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 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033518

Device Name: Lotus Pulmonary Function Filter

Indications For Use:

The Custom Plastic Products Pulmonary Function Filter is intended to reduce cross-contamination between the patient and the spirometers and pulmonary function testing instruments.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 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)

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

510(k) Number: K033518