510(k) SUMMARY – DYNAMIC BUBBLE TRAP

Submitter Name:	Convergenza AG
Submitter Address:	St. Markusgasse 16 FL 9490 Vaduz Principality of Liechtenstein
Contact Person:	Christie DeWitt
Phone/Fax Number:	(239) 992-3163
Date Prepared:	April 25, 2003
Device Trade Name:	DBT™, Dynamic Bubble Trap
Device Common Name:	Arterial Filter
Classification Name:	Cardiopulmonary Bypass Arterial Line Blood Filter 21 CFR §870.4260; Class II
Predicate Devices:	Pall EC Plus Filter (K834380)
Device Description:	The DBT™, Dynamic Bubble Trap is a sterile device with a non-pyrogenic fluid pathway. It is intended for single use only, in the arterial line of an extracorporeal circuit during cardiopulmonary bypass procedures. It is designed to remove gaseous microemboli from the arterial line of a cardiopulmonary bypass circuit.
Intended Use:	The DBT™ is indicated for use in cardiopulmonary bypass procedures for the removal of gaseous microemboli.
Device Technological Characteristics:	The DBT™ is tubular with 3/8-inch barbed inlet and outlet ports. Within the tube there is a diffuser chamber and a site for collecting microbubbles, which is connected to the recirculation line. Inside the diffuser chamber there is a tightly integrated three-channel spiral. As blood passes through the spiral, it is converted into a rotating stream. The resulting centripetal forces direct gaseous microemboli to the center of the flow line. The collection site, which is situated in the center of the distal end of the tube, diverts the central blood flow line and returns it together with all collected microbubbles to the cardiotomy reservoir.

Performance Data:	Testing was performed in accordance with the Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions, dated November 29, 2000. The recommended special controls have been applied to minimize all identified potential risks to health. Bench testing demonstrates that the device has been designed to minimize the identified potential risks to a patient's health.
Conclusion:	Based upon the performance studies and the proposed device labeling, the DBT™, Dynamic Bubble Trap, is substantially equivalent to the identified predicate devices in terms of intended use, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2003

Convergenza AG
c/o Ms. Christine B. DeWitt
DeWitt Group International
3625 Woodlake Drive
Bonita Springs, FL 34134

Re: K031323
DBT™, Dynamic Bubble Trap
Regulation Number: 870.4260
Regulation Name: Cardiopulmonary Bypass Arterial Line Blood Filter
Regulatory Class: Class II (two)
Product Code: DTM
Dated: April 24, 2003
Received: April 25, 2003

Dear Ms. DeWitt:

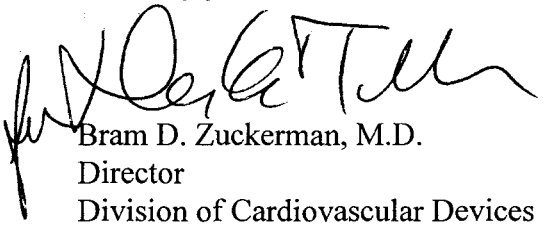
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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,



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): K031323

Device Name: DBT™, Dynamic Bubble Trap

Indications for Use:

The DBT™ is indicated for use in cardiopulmonary bypass procedures for the removal of gaseous microemboli.

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031323