

510(k) Summary
for the
theraPORT[®] Low-Profile Vascular Access System

K974475

MAR - 2 1998

GENERAL INFORMATION:

Common/Usual Names: Implanted Subcutaneous Intravascular Catheter;
Implantable Vascular Access System; Implanted
Infusion Port.

Proprietary Name: **theraPORT[®]** Low-Profile Vascular Access System

Applicant: Biocontrol Technology, Inc.
300 Indian Springs Road
Indiana, PA 15701
(412)349-1811

Equivalence Device Comparison: Bard Access
Systems, BardPort[®] Titanium Low-Profile, Product
Code 0606200; Cook Vascular, Inc., Vital-Port[®]
Model 6113; SIMS Deltec, Inc., Port-A-Cath[®] Low
Profile Unassembled, Kit No. 21-4034; Biocontrol
Technology, Inc., **theraPORT[®]** Vascular Access
System, Models 1001 and 1002.

DEVICE DESCRIPTION:

The **theraPORT[®]** Low-Profile Vascular Access System is a totally implantable venous access system consisting of a detached catheter and port.

INTENDED USE:

The **theraPORT[®]** Low-Profile Vascular Access System is intended for use with patients that require repeated venous access for injection or infusion therapy and/or venous blood sampling. It is indicated for either traditional chest placement or placement in the upper arm, and is appropriate for use in pediatric patients.

ALTERNATIVE DEVICES:

Alternative devices to the *theraPORT*[®] Low-Profile Vascular Access System are other commercially available implantable vascular venous access systems such as the BardPort[®] Titanium Low-Profile, Product Code 0606200, by Bard Access Systems; the Vital-Port[®] Model 6113, by Cook Vascular, Inc.; the Port-A-Cath[®] Low Profile Unassembled, Kit No. 21-4034, by SIMS Deltec, Inc.; and the *theraPORT*[®] Vascular Access System, Model 1001, by Biocontrol Technology, Inc.

POTENTIAL ADVERSE EFFECTS:

The following adverse effects, which are normally associated with the insertion or use of any implanted device or indwelling catheter, may occur when using the *theraPORT*[®] Low-Profile Vascular Access System: air embolism, bacteremia, catheter disconnection, catheter fragmentation, cardiac arrhythmia, cardiac puncture, cardiac tamponade, catheter occlusion, catheter rupture, catheter shearing, catheter/port erosion through blood vessel/skin, catheter/port migration, drug extravasation, hematoma, hemothorax, implant rejection, infection, laceration or puncture of vessels, pneumothorax, sepsis, thromboembolism, thrombophlebitis, thrombosis.

SUMMARY OF STUDIES:

Performance Testing:

Performance testing of the *theraPORT*[®] Low-Profile Vascular Access System was conducted in accordance with the "Guidance on 510(k) Submissions for Implanted Infusion Ports," Center for Devices and Radiological Health, Office of Device Evaluation, Division of Gastroenterology/Urology and General Use Devices, Food and Drug Administration, October 1990. Catheter-to-port connection strength tests, septum puncture durability tests, port leakage integrity tests and port/catheter clearance tests were all performed.

Biocompatibility testing was not conducted since all materials, their processing, and their sterilization are identical to substantially equivalent devices.

Clinical Studies:

Clinical studies were not conducted as they were determined to be not necessary due to the similarity in design, performance, materials, function and intended use of the *theraPORT*[®] Low-Profile Vascular Access System to other commercially available systems.

CONCLUSIONS DETERMINED FROM TESTS:

The above described studies demonstrate that the *theraPORT*[®] Low-Profile Vascular Access System functions properly and is substantially equivalent to the aforementioned commercially available predicate devices. Therefore, the *theraPORT*[®] Low-Profile Vascular Access System is determined to be safe and effective for its intended use.

theraPORT[®] is a registered trademark of Biocontrol Technology, Inc.

BardPort[®] is a registered trademark of C. R. Bard, Inc.

Port-A-Cath[®] is a registered trademark of SIMS Deltec, Inc.

Vital-Port[®] is a registered trademark of Cook Pacemaker Corp.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 1998

Patrick J. Cooper, Ph.D.
Manager, Sales and Marketing
Biocontrol Technology, Incorporated
300 Indian Springs Road
Indiana, Pennsylvania 15701

Re: K974475
Trade Name: theraPORT® Low-Profile Vascular Access
System, Models 1011 and 1012
Regulatory Class: Unclassified
Product Code: LJT
Dated: February 5, 1998
Received: February 6, 1998

Dear Dr. Cooper:

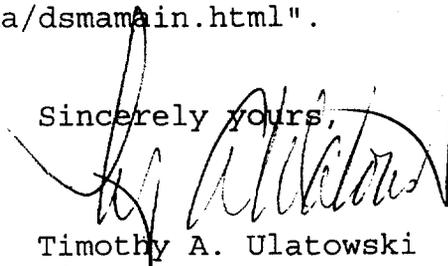
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the theraPORT® Low-Profile Vascular Access System have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of

the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmmain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K 974475

Device Name: theraPORT Low-Profile Vascular Access System

Indications for Use:

The **theraPORT** Low-Profile Vascular Access System is a totally implantable venous access system intended for use with patients that require repeated venous access for injection or infusion therapy and/or venous blood sampling. Because of its low-profile design, it is indicated for either traditional chest placement or placement in the upper arm, and is appropriate for use in pediatric patients and small adults.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert Curcote
(Division Signature)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K 974475

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)

PROPRIETARY/CONFIDENTIAL
BIOCONTROL TECHNOLOGY INC