K960350

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510(k) Summary
for the
***thera*PORT®** Vascular Access System

APR 15 1996

GENERAL INFORMATION:

Common/Usual Names:	Implanted Subcutaneous Intravascular Catheter; Implantable Vascular Access System; Implanted Infusion Port
Proprietary Name:	***thera*PORT®** Vascular Access System
Applicant:	Biocontrol Technology, Inc. 300 Indian Springs Road Indiana, PA 15701 (412)349-1811
Equivalence Device Comparison:	Cook Pacemaker Corporation, VITAL-PORT® Vascular Access Port with Detached Catheter; Pharmacia Deltec, Inc., PORT-A-CATH® Implantable Access System; and Therex, Inc., A-PORT® Implantable Vascular Access System.

DEVICE DESCRIPTION:

The ***thera*PORT®** Vascular Access System is a totally implantable venous access system consisting of a detached catheter and port.

INTENDED USE:

The ***thera*PORT®** is intended for use with patients that require repeated venous access for injection or infusion therapy and/or venous blood sampling.

ALTERNATIVE DEVICES:

Alternative devices to the ***thera*PORT®** Vascular Access System are other commercially available implantable vascular venous access systems such as the Cook Pacemaker Corporation, VITAL- PORT® Vascular Access Port with Detached Catheter, the Pharmacia Deltec, Inc. , PORT-A-CATH® Implantable Access System, and the Therex Corporation, A-PORT® Implantable Vascular Access System.

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 ***thera*PORT®** 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 ***thera*PORT®** 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 ***thera*PORT®** Vascular Access System to other commercially available systems.

CONCLUSIONS DETERMINED FROM TESTS:

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