SECTION VI: 510(k) SUMMARY
[as required by section 807.92(c)]

JAN - 4 2008

A. Submitter's Information:

Name:	Thomas Medical Products, Inc.
Address:	65 Great Valley Parkway Malvern, PA 19355
Telephone Number:	610.296.3000
Facsimile:	610.296.4591
Contact Person:	Tim Stoudt
Title:	Manager, QA Engineering / RA
Date Submission Prepared:	September 21, 2007

B. Device Information:

Trade name:	Not assigned at the time of submission
Classification Name(s):	Cardiopulmonary bypass adapter, stopcock, manifold, or fitting (21 CFR §870.4290)
Common or usual name(s):	Hemostatic Wye Adapter

C. Legally marketed device to which equivalence is claimed:

Guidant [Abbott] CoPilot Bleedback Control Valve – K991102

D. Description of the device:

The Thomas Medical Products Inc. Y-Glide™ Hemostatic Valve Wye Adapter contains a hemostasis valve with a secondary locking seal, a rotating luer lock, and a sideport. The primary hemostasis seal is opened by depressing the cap thereby enabling valve flushing, and a conduit for introduction and withdrawal of diagnostic/interventional devices. When the cap is not depressed, the seal returns to the closed position to allow device positioning with minimal fluid loss.

The secondary locking seal can be adjusted when the internal threads are engaged, by rotating the cap clockwise while slightly depressing it until the threads catch. Clockwise turns of the cap thereafter will close the locking seal. Rotating counterclockwise will open the locking seal. Closing the locking seal will secure the position of the inserted diagnostic/interventional device and/or permit pressure injections up to 450 psi (30.6 Atm.).

E. Intended use of the device:

The Y-Glide Hemostatic Valve Wye Adapter is to be used for maintaining a hemostatic seal around inserted devices with an outside diameter up to 0.120" (3.04 mm) during the use of diagnostic/interventional devices for transluminal procedures.

F. Summary of the technological characteristics of the device compared to the predicate device:

The technological characteristics of the device are the same or very similar to those of the predicate device.

G. Substantial equivalence rationale:

Visual and physical inspection as well as technical analysis of the legally marketed predicate device (Guidant CoPilot, K991102) compared with the TMP Y-Glide Hemostatic Wye Adapter (K072745) demonstrates that;

(1) the two devices have the same intended use,
(2) the two devices have the same or similar technical characteristics, and
(3) where the technical characteristics differ;
    (a) no new types of safety or effectiveness issues are raised, and
    (b) the technical analysis of the differences demonstrate that the TMP Y-Glide is as safe and effective as the legally marketed device (the converse is also true that the TMP Y-Glide is as un-safe and ineffective as the legally marketed device).

Elements of comparison include:
- Visual comparison
- Indication for use
- Instructions for use
- Sterility
- Design and performance
- Energy used or delivered
- Materials
- Biocompatibility
- Manufacturing processes
- Packaging
- Labeling
- Safety and effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2008

Thomas Medical Products, Inc.
c/o Mr. Tim Stoudt
Manager, QA/RA
65 Great Valley Parkway
Malvern, PA 19355

Re: K072745
Y-Glide™ Hemostatic Wye Adapter
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary bypass adaptor, stopcock, manifold or fitting
Regulatory Class: Class II (two)
Product Code: DTL
Dated: May 25, 2007
Received: September 27, 2007

Dear Mr. Stoudt:

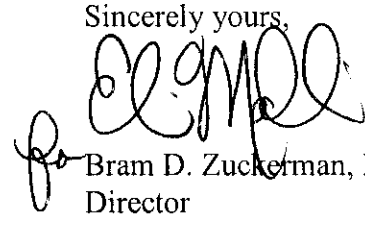
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT: INDICATION FOR USE

510 (k) Number: K072745

Device Name: Y-Glide™ Hemostatic Wye Adapter

Indications for Use:

The Y-Glide™ Hemostatic Wye Adapter is to be used for maintaining a hemostatic seal around inserted devices with an outside diameter up to 0.120" (3.04 mm) during the use of diagnostic/interventional devices for transluminal procedures.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) and/or Over the Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072745