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510(K) SUMMARY

MAR - 6 2009

1) **Submitter's Name:**

TransCardiac Therapeutics Inc

3355 Lenox Road NE Suite 415

Atlanta, GA 30326

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Fax: 404-816-4530

Contact Person (s):

Primary Contact Person	**Secondary Contact Person**
David Smith	Lina Lattouf
Chief Technology Officer	Vice President
Tel: 404-816-4520 ext 105	Scientific & Regulatory
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Establishment registration number: TBD

Date the summary was prepared: 10-27-2008

2) **Device Identification:**

Proprietary Name:	TC Endo Port
Common Name:	Endoscope and Accessories
Classification Name:	Endoscope and Accessories
Classification Number:	21 CFR 876.1500
Classification Panel:	Gastroenterology and Urology
Product Code:	GCJ

Regulatory Class: II

3) Legally marketed device to which equivalence is claimed:

Manufacturer: Ethicon Endo-Surgery

Device Name: Endopath Trocar System

510(K) Identification: K032676.

4) DEVICE DESCRIPTION

TC Endoport trocars are sterile single patient use instruments consisting of a sleeve and obturator in sizes ranging from 5-12 mm in diameter. The TC Endoport obturator is made from plastic, and has a dilator tip which gently moves aside any internal viscera that may be adjacent to the abdominal or thoracic wall.

The trocar sleeve contains two seals, an outer annular seal that accommodates instruments from 5-12 mm in diameter, and an internal seal. Together these seals minimize gas or fluid leakage when instruments are inserted or withdrawn through the trocar. A stopcock valve, or valved luer are provided with standard luer lock fittings, to provide for gas insufflation, desufflation, or infusion and aspiration of fluids.

The device depiction section provides a more detailed description of the device, and the predicate.

5) Statement of Intended Use

The TC Endo Port has applications in abdominal, thoracic, laparoscopic and gynecologic minimally invasive procedures to establish a path of entry for endoscopic instruments.

6) Technological Characteristics

a) Summary of technological characteristics of the TC Endo Port compared to the predicate device

The technological characteristics of the new device are different from the predicate in that the trocar securement mechanism is created through the use of inflatable balloons placed along the trocar shaft instead of barbs as in the predicate device. This provides for a secure hemostatic seal, and allows for the device to be customized for different patient needs.

b) Assessment of Performance Data

1) Summary of the non-clinical performance data

The following non-clinical tests were performed as the basis for establishing substantial equivalence to the predicate device, as well as safety and effectiveness of the indication for use:

Test Name	Sample Size	Test Description	Required Results
Sterilization Exposure	All	The samples are exposed to a 2X sterilization cycle.	All samples must be capable of withstanding a 2Xsterilization cycle.
Simulated implant	30 1 Pred	Simulate placing the device using an implant simulator. Measure insertion forces and compare to predicate device	All samples must be capable of being implanted in simulated conditions using the instructions for use. Insertion forces must be equal to or less than predicate device
Valve tool pass verification	30	Pass tools of various size through the distal valve and verify that tools can be accommodated without damage or excessive leakage	Must pass the range of recommended tools through the valve without damaging the valve or causing the loss of more than 10ml of fluid
Valve cyclic test	30	Pass tools through the valves repeatedly until failure occurs or maximum number of tool passes requirement is reached	Must pass the maximum sized tool through the valve ten times without damaging the valve or causing the loss of

			more than 10ml of fluid
Valve pressure withstand	30	Determine that valves meet the minimum pressure requirement without failure. Compare to predicate device	Must withstand a fluid pressure of 450mmHg without leaking
Balloon diameter verification	30	Measure the inflated diameter and length of the distal and proximal balloons when fully inflated	Profile of balloons must be within 15%-25% of expected values from design
Balloon volume loss	30	Determine that volume loss of balloons over time is within specification	Balloons cannot lose more than 0.5ml over one hour
Balloon inflation/ deflation time	30	Measure time required to inflate and deflate balloons	Balloons must inflate and deflate in under 15 seconds
Balloon cyclic test	30	Repeatedly inflate/deflate balloons until failure occurs or minimum number of cycles required is reached	Balloons and inflation lumens must withstand 40 inflation/deflation cycles to 1 atm without failure.
Balloon minimum burst strength	30	Measure burst pressure and volume. Verify that minimum is achieved	Balloon should withstand 2X SF over 1 atm
Cannula to hub strength	30	Measure tensile forces. Verify that minimum is achieved	Material interface should resist a tensile force of up to 3.4 lb (15 N).
Inflation lumen to hub strength	30	Measure tensile forces. Verify that minimum is achieved	Material interface should resist a tensile force of up to 3.4 lb (15 N).
Valve body to cannula strength	30	Measure tensile forces. Verify that minimum is achieved	Material interface should resist a tensile force of up to 3.4 lb (15 N).
Dilator insertion/removal force	30	Measure insertion removal forces, verify that forces are less than tensile forces	Material interface should resist a tensile force of up to 3.4 lb (15 N).

The TC Endo port and components are packaged in industry-standard, EtO gas-permeable sterile barrier materials using industry-standard package sealing processes. The packaging is an inner tray containing the port, and introducer components sealed with a Tyvek lid within an outer tray that is also sealed with a Tyvek lid.

2) No clinical tests were conducted as part of this products development.

3) SUMMARY OF CONCLUSIONS

The TC Endo Port and the predicate devices have identical intended uses and fundamental scientific technology. The subject and predicate devices are substantially similar in configuration, dimensions, and materials. No new questions of safety or effectiveness were raised during the performance testing of the device. The TC Endo Port has been determined to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

TransCardiac Therapeutics, Inc.
% Mr. David Smith
VP and Chief Technology Officer
3355 Lenox Road North East, Suite 415
Atlanta, Georgia 30326

MAR - 6 2009

Re: K083218
Trade/Device Name: TC Endo Port
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 6, 2009
Received: February 9, 2009

Dear Mr. Smith:

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.

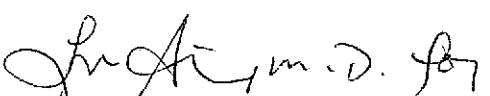
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known):

Device Name: TC Endo Port

Indications for Use:

The TC Endo Port has applications in abdominal, thoracic, laparoscopic and gynecologic minimally invasive procedures to establish a path of entry for endoscopic instruments.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083218