MAY 2 8 2004

510(k) Summary of Substantial Equivalence

Date Prepared	March 01, 2004 K040552
Submitter	CryoCor, Inc.
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E-Mail Address	jmiller@cryocor.com
Device Trade Name/ Model Numbers	Model 3100 Series Sheath Kits Model 3110 Model 3130
Device Common Name	Catheter Introducer
Device Classification Name	Catheter Introducer
Classification Regulation	Class II, C.F.R. Section 870.1340
Product Code	DYB

Device Description

The Model 3100 Series Sheath Introducer Kit consists of various sheath introducers, each packaged in a kit together with a dilator, introducer catheter and guide wire.

The sheath introducer is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A side port with three-way stopcock is provided for air aspiration, fluid infusion, blood sampling and pressure monitoring. A radio-opaque marker at the tip of the sheath will aid during placement while utilizing fluoroscopic guidance. There are side holes at the distal end to allow for injection of contrast media.

The dilator is tapered at the distal tip to allow for use of standard needles for trans-septal procedures, and will accommodate a guide wire or needle no larger than 0.038".

The introducer catheter is gradually tapered distally to allow for gradual dilation of entry into vasculature without producing damage.

The guide wire is 0.038" in diameter, 150 cm in length with a "J"-tip configuration. It is supplied in a hoop dispenser with a "J" straightener attached to the distal end. The proximal end of the hoop dispenser has a luer hub to facilitate flushing of the wire.

Intended Use

The CryoCor Model 3100 Series Sheath Kits are intended to facilitate the percutaneous introduction of cardiovascular catheters into the heart, while preventing backflow of blood.

Substantially Equivalent Devices

The Model 3100 Series Sheath Kits are substantially equivalent to the Daig Fast-Cath Intra-Cardiac Introducer cleared under K973840 and the Daig Fast-Cath Transseptal Introducer cleared under K964518.

The physical characteristics, the intended use, and the mode of use of the Model 3100 Series Sheath Kits are similar to the predicate device.

Test Summary

Performance Testing
Bench testing confirmed that the Model 3100 Series Sheath Kits met all of its design and performance requirements.

Pre-Clinical Studies
Comparison testing found that the Model 3100 Series Sheath Kits performed at least as well as the predicate device.

Biocompatibility Information
Biocompatibility testing was performed on the materials which are blood contacting according to ISO 10993-1. All materials were found to be biocompatible.

Sterilization Validation
The Model 3100 Series Sheath Kits are sterilized using a validated E-beam radiation sterilization cycle.

Conclusion

CryoCor, Inc. considers the Model 3100 Series Sheath Kits to be substantially equivalent to their legally marketed predicate device based on the data and information presented within this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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CryoCor, Inc.
c/o Ms. Jami Miller
Regulatory Affairs Specialist
9717 Pacific Heights Blvd.
San Diego, CA 92121

Re: K040552
Model 3100 Series Sheath Kits
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 1, 2004
Received: March 2, 2004

Dear Ms. Miller:

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) 594-4648. 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,

Donna R. Bachner

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

Indications for Use

510(k) Number: K 040552

Device Name: Model 3100 Series Sheath Kits

Indications for Use:

The CryoCor Model 3100 Series Sheath Kits are intended to facilitate the percutaneous introduction of cardiovascular catheters into the heart, while preventing backflow of blood.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040552