K963503

APR -3 1997

510(k) Summary
CardioThoracic Systems, Inc.
CTS MIDCAB™ Coronary Shunt
510(k) Notification K 963503

GENERAL INFORMATION

Manufacturer: CardioThoracic Systems, Inc.
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Cupertino, California
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Est. Reg. No. (awaiting issuance)

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Date Prepared: August 31, 1996

DEVICE DESCRIPTION

Classification: Class II

Trade Name: CTS MIDCAB Coronary Shunt

Generic/Common Name: Vascular clamp 870.4450
Surgical vessel dilator 870.4475
Blood access device and accessories 876.5540

PREDICATE DEVICES

(1) Bio-Vascular, Inc. Flo-Rester
(2) Research Medical, Inc. Yacoubian Clamp External Coronary Artery Occluder
(3) Research Medical, Inc. Carotid Artery Shunts
(4) Research Medical, Inc. Vacu-Sponge Surgical Sponge

INTENDED USE

The CTS MIDCAB Coronary Shunt is intended to be used during minimally invasive direct coronary artery bypass ("MIDCAB") procedures in conjunction with or without the CTS MIDCAB™ Access Platform and Stabilizer. The CTS Coronary Shunt is designed to help reduce blood in the operative field by temporary occlusion of the artery and to provide blood flow distal to the arteriotomy. This CTS Coronary Shunt is not an implant and is removed prior to completion of the surgery.

PRODUCT DESCRIPTION

The CTS MIDCAB Coronary Shunt is a hollow tube with atraumatic tips on each end and two seals which are utilized for proximal and distal occlusion of the artery. The atraumatic tips are tapered for easy insertion and removal from the artery. Each tip contains holes to provide for blood flow into and out of the CTS Shunt. The thread or tether is attached to a tab and is used to aid insertion and removal of the CTS Shunt. The blood is occluded and flows through the Shunt which reduces the blood in the operative field. Also included with the CTS MIDCAB Coronary Shunt is a Shunt Remover, which is a cylinder which can be used to withdraw the CTS Shunt following completion of the procedure.

SUBSTANTIAL EQUIVALENCE

The CTS MIDCAB Coronary Shunt is substantially equivalent to predicate devices currently being marketed. The marketed predicate devices are identified above. The CTS MIDCAB Coronary Shunt is substantially equivalent to the predicate devices with regard to intended use, function, physical characteristics, materials and sterilization method.

All necessary testing was performed on the CTS MIDCAB Coronary Shunt to ensure the product is substantially equivalent to the predicate devices and to ensure that the CTS Coronary Shunt does not have any differences which have a significant effect on safety and effectiveness.

FUNCTIONAL PERFORMANCE TESTING

Functional testing was conducted on the CTS MIDCAB Coronary Shunt to ensure that the Shunt would function according to its intended use instructions. All testing conducted confirmed the acceptability of the CTS Shunt to perform as intended to help reduce blood in the operative field by temporary occlusion of the artery while providing blood flow distal to the arteriotomy.

BIOCOMPATIBILITY EVALUATION

The biocompatibility testing was conducted on the CTS MIDCAB Coronary Shunt and Shunt materials to ensure the acceptability of the CTS MIDCAB Coronary Shunt when used as directed. The CTS Shunt and Shunt materials passed the necessary biocompatibility tests.

SUMMARY

As contained in this 510(k) summary, all necessary testing was conducted on the CTS MIDCAB Coronary Shunt to ensure that the device is safe and effective when used in accordance to its intended use.