

K982419

JAN 13 1999

**510(k) Summary
CardioThoracic Systems, Inc.
Heart-LIFT Balloon Positioner
510(k) Notification K982419**

GENERAL INFORMATION

Manufacturer: CardioThoracicSystems, Inc.
10600 North Tantau Avenue
Cupertino, California
(408) 342-1700
(408) 342-1717 FAX
Est. Reg. No. 9027735

Contact Person: Michael J. Billig
Vice President, Regulatory, Quality, and Clinical
Research

Date Prepared: July 08, 1998

DEVICE DESCRIPTION

Classification: Cardiovascular Surgical Instruments 21 CFR
870.4500 (510(k) exempt)

Trade Name: CTS Heart-LIFT™ Balloon Positioner

Generic/Common Name: Heart Positioner; Cardiovascular Surgical
Instrument

PREDICATE DEVICES

Janke-Barron Heart Support manufactured by Baxter

INTENDED USE

The CTS Heart-LIFT Balloon Positioner is a surgical instrument intended to lift and position the heart during cardiac surgery.

PRODUCT DESCRIPTION

The CTS Heart-LIFT Balloon Positioner consists of a manually inflatable, latex-free balloon attached to a malleable shaft. The balloon is inflated using a hand pump,

which is attached via a flexible air tube to the proximal end of the malleable shaft. A pressure release valve allows deflation of the balloon. There also is a pressure relief valve to prevent over-inflation.

SUBSTANTIAL EQUIVALENCE

The CTS Heart-LIFT Balloon Positioner is a surgical instrument intended to lift and position the heart during cardiac surgery. The Heart-LIFT Balloon Positioner is substantially equivalent to the Baxter Janke-Barron Heart Support in regards to intended use, patient population and anatomical site. The predicate device is a Class I pre-amendment device.

Functional bench testing and animal testing has been conducted and the results of the testing verified that the Heart-LIFT Balloon Positioner performs as designed and is suitable for its intended use.

SUMMARY

As contained in this 510(k) summary, the CTS Heart-LIFT Balloon Positioner is substantially equivalent to the predicate device identified in that the Heart-LIFT Balloon Positioner has a similar intended use, patient population and anatomical site as the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 1999

Mr. Michael J. Billig
Vice President, Regulatory, Quality, and
Clinical Research
CardioThoracic Systems, Inc.
10600 North Tantau Avenue
Cupertino, CA 95014

Re: K982419
Heart-Lift Balloon Positioner
Regulatory Class: I
Product Code: 74 MWS
Dated: October 20, 1998
Received: October 21, 1998

Dear Mr. Billig:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to

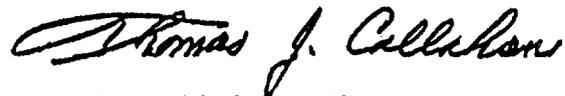
Page 2 - Mr. Michael J. Billig

your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Premarket Notification
CTS Heart-LIFT Balloon Positioner

CardioThoracic Systems, Inc.
CTS Heart-LIFT Balloon Positioner
510(k) Premarket Notification

STATEMENT OF INDICATIONS FOR USE

The CTS Heart-LIFT Balloon Positioner is a surgical instrument intended to lift and position the heart during cardiac surgery.


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982419
* For Prescription Use Only

P.S. This is
a prescription
device.