2/23/99

K983471

9 510(K) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and CFR 21 §807.92.

Submitter's Information:

Name:	RADI Medical Systems AB
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Contact Person:	Mats Granlund
Date of Preparation:	September 30, 1998

Device Name:

Trade Names:	FemoStop® System.
Common Name:	Femoral Compressor Device.
Classification Name:	Clamp

Predicate Device Names: FemoStop® System (K954669)
FemoStop® II PLUS System (K982182)

Device Description:
The FemoStop System consists of an arch with a sterile pneumatic pressure dome, a connection tubing and belt, a reusable pump with manometer and an optional adapter for bilateral compression. The device is applied on the patient with the dome over the groin and the belt around the patient. The user controls the inflation of the dome by increasing or decreasing the pressure with the connected pump. Then the dome applies a mechanical pressure over the spot where there is a bleeding to stem, while the arch and belt absorb and evenly distribute the opposite force from the dome.

Intended Use:
The FemoStop® system is indicated for use in the compression of the femoral artery or vein after vessel cannulation, and in ultrasound-guided compression repair of a femoral artery pseudoaneurysm.

Technical Characteristics Summary:
Subject device has the same technology, and is manufactured with parts of the predicate devices.

Performance Data:
Due to the extreme similarity in design and materials between subject and predicate devices further performance testing has not been considered necessary.
Published journal articles on the subject "ultrasound-guided compression repair of pseudoaneurysm " with usage of compression devices such as FemoStop have been reviewed as input to the product labeling.

Conclusions
The conclusions drawn from the clinical studies is that the subject device is suitable to replace the ultrasound-probe or other compression technique at ultrasound-guided compression repair of pseudoaneurysm".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 1999

Mr. Mats Granlund
RADI Medical Systems AB
Palmbladsgatan 10
SE-754 50 UPPSALA
SWEDEN

Re: K983471
Trade Name: FemoStop® System
Regulatory Class: II
Product Code: DXC
Dated: December 15, 1998
Received: December 23, 1998

Dear Mr. Granlund:

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 (Premarket 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 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

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

Enclosure

2 Statement of Indications for Use

510(k) Number: K983471

Device Name: FemoStop® System

Indications for Use: The FemoStop® system is indicated for use in the compression of the femoral artery or vein after vessel cannulation, and in ultrasound-guided compression repair of a femoral artery pseudoaneurysm.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____