K980898

APR 21 1998

SECTION IV
510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
FEMOSTOP® II PLUS SYSTEM

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 Quality Manager
Date of Preparation:	March 6, 1998

Device Name:

Trade Names:	FemoStop®II^{PLUS} System with FemoStop®II^{PLUS} Disposable Set, FemoStop®II Compression Arch, FemoStop®II Pump and FemoStop®II Bilateral Adapter
Common Name:	Femoral Compressor Device
Classification Name:	Not known

Predicate Device Names: FemoStop®II System with FemoStop®II Disposable Set, FemoStop®II Compression Arch and FemoStop®II Pump

Device Description:

The FemoStop II^{PLUS} System consists of a single use compression dome attached to an arch which is located on the patient together with a belt. The pump is connected to the dome to manually control the pressure over the femoral artery/vein puncture site. The bilateral adapter facilitates simultaneous compression of both the left and right side.

Intended Use:

The FemoStop II^{PLUS} System is indicated in the compression of the femoral artery or vein after catheterization.

Technical Characteristics Summary:

The FemoStop II^{PLUS} System is very similar to FemoStop II System, rearding materials, construction, packaging, sterilization and indication for use.

Performance Data:

Safety and performance testing was performed to demonstrate that the FemoStop®II^{PLUS} System. The minor change in packaging has addressed in an identical as the predicate device which the same satisfying results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 1998

Mr. Mats Granlund
Quality Manager
Radi Medical Systems AB
Palmbladsgatan 10
S-754 50 Uppsala, Sweden

Re: K980898
Trade Name: FemoStop®II^{PLUS} System
Regulatory Class: II
Product Code: DXC
Dated: March 6, 1998
Received: March 9, 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) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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

INDICATIONS FOR USE

510(k) Number: _____

Device Name: FemoStop®II^{PLUS} System

Indications for Use: The FemoStop®II^{PLUS} System is indicated in the compression of the femoral artery or vein after catheterization.

(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)

(Optional Format 1/2/96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K980898