

1024107

DEC 24 2002

## Attachment 4

### 510(k) Summary

This 510(k) summary is submitted in accordance with the requirements in 21 CFR §807.92

Submitted by: RADI Medical Systems AB  
Palmladsgatan 10  
SE-754 50 Uppsala, Sweden  
Phone:(+46) 18161000

Contact Person: Mats Granlund

Date Prepared: December 10, 2002

Proprietary Name: FemoStop® Femoral Compression System

Common Name: Femoral compression device

Classification Name: Clamp, DXC

Predicate Devices: K954669 FemoStop® System  
K982182 FemoStop®II System  
K983471 FemoStop®<sup>PLUS</sup> System  
K010933 Seal-On Hemostatic Powder Spray  
K920796 DeRoyal Transparent Film Dressing (Transeal)  
K962425 Bonopty Coaxial Bone Biopsy System

Description of the Device: The FemoStop®Femoral Compression System consists of an arch with a sterile pneumatic pressure dome attached to an arch, a belt, and a reusable pump with manometer. With this application a sterile hemostatic dressing, HD, is added to the system. The dressing has an active agent made of calcium/sodium salt of micro dispersed oxidized cellulose for topical control of bleeding.

Indication for Use of the Device: FemoStop® Femoral Compression 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: The technical characteristics of the actual FemoStop, i.e. are identical to those predicate devices cleared the previous FemoStop applications.

The technical characteristics of the hemostatic dressing - permeable to moisture allowing the skin to breathe but impermeable to water and bacteria, functioning as a bacterial barrier - are substantially equivalent to Transeal, DeRoyal Transparent Film Dressing (K920796) and the technical characteristics of the active substance - induce topical control of bleeding - are substantially equivalent to Seal-On Hemostatic Powder Spray (K010933). The technical characteristics of the



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 24 2002

RADI Medical Systems AB  
c/o Mr. Mats Granlund  
Palmladsgatan 10  
SE-754 50 Uppsala, Sweden

Re: K024107  
FemoStop® Femoral Compression System  
Regulation Number: 870.4450  
Regulation Name: Vascular Clamp  
Regulatory Class: Class II (two)  
Product Code: DXC  
Dated: December 10, 2002  
Received: December 13, 2002

Dear Mr. Granlund:

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) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



for

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

Enclosure

## Attachment 2

### Indication for Use Statement

510(k) Number:

K024107

Device Name:

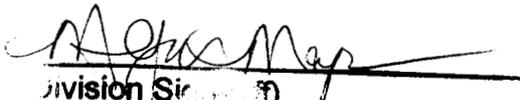
FemoStop® Femoral Compression System

Indications for Use:

FemoStop® Femoral Compression System is indicated for use in the compression for the femoral artery or vein after vessel cannulation, and in ultrasounded-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)

*for B02*  
  
Division of Cardiovascular Devices  
510(k) Number K024107

Prescription Use \_\_\_\_\_

OR

Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)