RADI Medical Systems AB
Helene Ekstrand
Regulatory Affairs Officer
Palmbladsgatan 10
SE-754 50 Uppsala
Sweden

June 11, 2023

Re: K033291
Trade/Device Name: TopSeal™ Hemostatic Dressing
Regulatory Class: Unclassified
Product Code: QSY

Dear Helene Ekstrand:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 17, 2004. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSY.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2004

Ms. Helene Ekstrand
Regulatory Affairs Officer
RADI Medical Systems AB
Palmbladsgatan 10
SE-754 50 Uppsala, Sweden

Re: K033291
Trade/Device Name: TopSeal™ Hemostatic Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 14, 2004
Received: January 16, 2004

Dear Ms. Ekstrand:

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) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033291

Device Name: TopSeal™ Hemostatic Dressing.

Indications For Use: TopSeal™ Hemostatic Dressing is indicated for control of minor bleeding from wounds and lacerations or minor bleeding from skin incisions or punctures following percutaneous medical procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033291

K033291 8E 1 of 1

MAR 17 2004

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
Address:	Palmbladsgatan 10, SE-754 50 Uppsala, Sweden
Phone/Fax:	+ 46 18 16 10 00/ + 46 18 16 10 99
Contact Person:	Helene Ekstrand
Date of Preparation:	October 10th, 2003

Device Name:

Trade name:	TopSeal™ Hemostatic Dressing
Common name:	Dressing
Regulatory Class:	Unclassified
Product Code:	FRO

Predicate Device Names:

FemoStop®HD (K024107)
HemaDerm™ (K021678)
Hemosorb (K021581)

Device Description:

TopSeal™ Hemostatic Dressing is a sterile dressing impregnated with the hemostatic agent m.doc™ (calcium/sodium salt of micro-dispersed oxidized cellulose). The active hemostatic agent promotes the topical control of bleeding.
TopSeal™ Hemostatic Dressing is also impermeable to water and bacteria and acts as a bacterial barrier.

Indication for Use:

TopSeal™ Hemostatic Dressing is indicated for control of minor bleeding from wounds and lacerations or minor bleeding from skin incisions or punctures following percutaneous medical procedures.

Technical Characteristics Summary:

TopSeal™ Hemostatic Dressing is a sterile dressing is identical to the hemostatic dressing incorporated into the FemoStop®HD Femoral Compression System. The pad is made of absorbent, non-woven, viscose-polyolefin layer, impregnated with a hemostatic agent (calcium/sodium salt of micro-dispersed oxidized cellulose) and covered with a non-adhesive, non-woven polyester wound contact layer.