

510(k) Summary

Submitted by: Entegriion, Inc.
79 Alexander Drive, Suite 200
4401 Research Commons
Research Triangle Park, NC 27709
(919) 536-1500 (phone)
(919) 536-1700 (fax)

Contact: Stan Eskridge
President and CEO
(919) 423 6050 (cell)
stan.eskridge@entegriion.com

DEC 1 0 2007

Prepared on: October 9, 2007

Device name: Stasilon™
Trade name: Stasilon FR™
Common name: Traumatic Wound Dressing, Topical Hemostat
Classification name: Wound Dressing, Drug
Product Code: FRO
Device Class: Unclassified

Predicate Device Trade Name (510(k) Number)	Product Code
HemCon Bandage and HemCon OTC (K043050)	FRO
QuikClot ACS (K051955)	FRO
D-Stat Dry Hemostatic Bandage (K061219)	FRO, DXC
Syvekexcel (K053300)	DXC

Device Description

Stasilon™ is a textile technology that is manufactured from two component yarns: continuous filament fiber glass yarn and bamboo yarn. It is woven to a specific width and cut to length. The cut edges are sealed with a small amount of high melt temperature pure paraffin wax. The device is typically finished as a flat, four-inch square (4"x4"), single-layer pad that is individually packaged, sealed and Gamma sterilized at 25 kGy (SAL 10⁻⁶) and sold under the trade name Stasilon FR™.

The component yarn materials and proprietary weave provide wound protection, reduce blood loss after contact with the wound, and help retain clot integrity during removal. The device shows superior performance when compared to the gauze control in animal models.

Intended Use

OTC

Stasilon FR™ is indicated to temporarily control bleeding in minor cuts, lacerations, punctures, abrasions and incisions.

RX

Stasilon FR™ is a single-use hemostatic wound dressing applied externally with mechanical compression to temporarily control bleeding in lacerations, punctures, abrasions and incisions.

Substantial Equivalence Comparison Summary

Entegriion, Inc. has submitted information on indications for use, method of operation, composition, sterilization, packaging, labeling, and performance to establish that Stasilon FR™ is substantially equivalent to the currently marketed predicate devices. Stasilon FR™ has essentially the same intended use as the predicate devices, has successfully completed biocompatibility testing, and has been shown to provide hemostasis in animal models.

END OF SUMMARY



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 2007

Entegron, Inc.
% Mr E. S. Eskridge, Jr.
President
79 TW Alexander Drive, Suite 20
4401 Research Commons
Research Triangle Park, North Carolina 27709

Re: K072890
Trade/Device Name: Stasilon FR™
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 10, 2007
Received: October 10, 2007

Dear Mr. Eskridge:

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.

Page 2 – Mr E. S. Eskridge, Jr.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
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): _____

Device Name: Stasilon FR™

Indications for Use:

Stasilon FR™ is a single-use hemostatic wound dressing applied externally with mechanical compression to temporarily control bleeding in lacerations, punctures, abrasions and incisions.

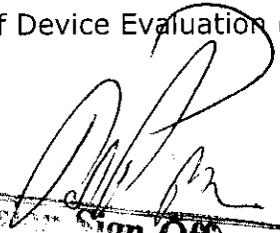
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Director Sign-Off)

General, Restorative, and Neurological Devices 1 of 1

(Posted November 13, 2003)

510(k) 1072890

K072890 111

Indications for Use

510(k) Number (if known): _____

Device Name: Stasilon FR™

Indications for Use:

Stasilon FR™ is indicated to temporarily control bleeding in minor cuts, lacerations, punctures, abrasions and incisions.

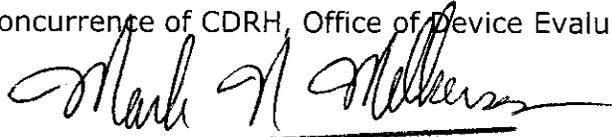
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K072890

Page 1 of 1

(Posted November 13, 2003)