Wound Management
Smith & Nephew, Inc.
970 Lake Carillon Drive
Suite 110
St. Petersburg, FL 33716

T 727 392-1261
F 727 392-6914 or 727 392-0797
Customer Care Center: 1 800 876-1261
www.smith-nephew.com



We are smith&nephew

**510(k) Summary**
**RENASYS™ -F/AB Abdominal Dressing Kit**
**510(k) # K100787**

SEP 17 2010

1. **Submitter:** Smith & Nephew, Inc.
   970 Lake Carillon Drive, Suite 110
   St. Petersburg, FL 33716

2. **Contact:** Laura D. Reynolds, RAC
   Regulatory Affairs Manager
   727-329-7702

3. **Date Prepared:** September 14, 2010

4. **Device Name:** RENASYS™ -F/AB Abdominal Dressing Kit
   **Common Name:** Abdominal Dressing Kit
   **Classification Name:** Mesh, Surgical, Polymeric, 21 CFR 878.3300
   **Product Classification/Code:** Class II, FTL

5. **Predicate Device Information:**

   V.A.C.® Abdominal Dressing
   KCI USA, Inc.
   510(k) # K022011

6. **Device Description:**

   The RENASYS™ -F/AB Abdominal Dressing Kit consists of two large hydrophobic reticulated polyurethane foam dressings that incorporate several cuts to facilitate custom sizing if needed. Also included in the kit are a polyurethane organ protection layer, six transparent film drapes and a suction port assembly with tubing that attaches to the exudate canister. The kit is designed specifically for abdominal wounds and is supplied sterile, single use.

   The RENASYS- F/AB Abdominal Dressing Kit is used in conjunction with Smith & Nephew RENASYS EZ and EZ PLUS negative pressure wound therapy pumps and canister kits, which have been previously cleared under 510(k) numbers K082426, K091470 and K102001.

7. **Intended Use:**

   The RENASYS- F/AB Abdominal Dressing Kit is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. It is intended to be used in open abdominal wounds with exposed viscera, including but not limited to abdominal compartment syndrome.

   This dressing kit is intended for use in acute hospital settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre.

8. **Summary of Non-Clinical Testing**

The following biocompatibility testing for all kit components has been successfully completed per applicable parts of ISO 10993:

| Kit Component | Tests Completed |
|---|---|
| Foam | Cytotoxicity<br>Irritation<br>Sensitization |
| Organ Protection Layer | Cytotoxicity<br>Irritation<br>Sensitization<br>Implantation<br>Sub-acute Toxicity<br>Genotoxicity |
| Transparent Film Drape | Cytotoxicity<br>Irritation<br>Sensitization |
| Suction Port Assembly | Cytotoxicity<br>Irritation<br>Sensitization<br>Sub-acute Toxicity<br>Genotoxicity |

Design verification testing has been conducted to demonstrate the device meets the performance specifications, delivers negative pressure wound therapy to the wound and removes exudates.

9. **Conclusions Drawn**

The RENASYS-F/AB Abdominal Dressing Kit has successfully undergone testing to demonstrate that the device is substantially equivalent to the predicate device and is safe and effective for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith and Nephew
% Ms. Laura Reynolds, RAC
Regulatory Affairs Manager
970 Lake Carillon Drive, Suite 110
St. Petersburg, Florida 33716

SEP 17 2010

Re: K100787
Trade/Device Name: Renasys™ F/-AB Abdominal Wound Dressing Kit
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: August 31, 2010
Received: September 1, 2010

Dear Ms. Reynolds:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

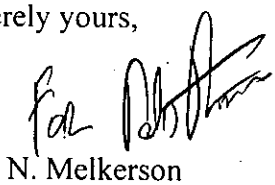
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K100787

Device Name: RENASYS™ F/- AB Abdominal Wound Dressing Kit

SEP 17 2010

Indications for Use:

The RENASYS™- F/-AB Abdominal Wound Dressing Kit is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. It is intended to be used in open abdominal wounds with exposed viscera, including but not limited to abdominal compartment syndrome.

This dressing kit is intended for use in acute hospital settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre.

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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100787