8. SUMMARY OF SAFETY & EFFECTIVENESS

Glenveigh™

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APR 14 2010

APPLICANT	Glenveigh Surgical, LLC 401 Chestnut Street, Suite 230 Chattanooga, TN 37402 Rick Proctor Tel: 423-243-3460 Fax: 423-634-8080 Email: rick.proctor@glenveigh.com
OFFICIAL CORRESPONDENT	Penny Northcutt, RAC, CQA Regulatory Consultant for Glenveigh Surgical REGSolutions, LLC Tel: 678-428-6978 Fax: 678-513-0937 Email: **pennynorthcutt@theregsolutions.com**
TRADE NAME:	Glenveigh Vaginal Repair Balloon Catheter
CLASSIFICATION NAME:	Obstetric-Gynecologic Specialized Manual Instrument
DEVICE CLASSIFICATION AND PRODUCT CODE	Class II per 21 CFR §884.4530 Product Code: KNA
PREDICATE DEVICE NAME	EpiStat/V-Stat Vaginal Tamponade Balloon (K060289) Cleared July 7, 2006 Gauze Packing

SUBSTANTIAL EQUIVALENCE:

The Glenveigh Vaginal Repair Balloon Catheter is substantially equivalent to the EpiStat/V-Stat Vaginal Tamponade Balloon cleared under K060289.

Both the Glenveigh Vaginal Repair Balloon Catheter and the predicate devices have the same method of operation, to temporarily block the flow of fluids to assist in episiotomy/laceration repair.

Bench testing has demonstrated that the Glenveigh Vaginal Repair Balloon Catheter is functionally equivalent to predicate EpiStat/V-Stat Vaginal Tamponade Balloon, and that any minor differences do not affect safety or effectiveness.

DESCRIPTION OF THE DEVICE:

The Glenveigh Vaginal Repair Balloon Catheter is a single lumen balloon-type catheter which temporarily blocks the flow of fluids to assist in episiotomy/laceration repair.

The device consists of the following main components: a vaginal balloon, a tubing/catheter shaft, and an inflation assembly.

INDICATIONS FOR USE:

The Glenveigh Vaginal Repair Balloon is indicated for use during episiotomy/vaginal laceration repair to temporarily prevent the post partum discharge of fluids from the vagina in order to assist with the episiotomy/laceration repair procedure.

PERFORMANCE DATA:

The Glenveigh Vaginal Repair Balloon Catheter materials that come in direct contact with the patient have a long history of use in medical use and are biocompatible according to ISO 10993. Design verification performance test results demonstrate that the Glenveigh Vaginal Repair Balloon Catheter performs its intended use and is equivalent to the predicate device.

CONCLUSION:

Based on the performance testing, it can be concluded that the Glenveigh Vaginal Repair Balloon Catheter is equivalent to the predicate EpiStat/V-Stat Vaginal Tamponade Balloon with respect to intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Glenveigh Surgical, LLC
c/o Ms. Penny Northcutt, RAC, CQA
Regulatory Consultant for Glenveigh Surgical
REGSolutions, LLC
717 Lakeglen Drive
SUWANEE GA 30034

APR 1 4 2010

Re: K093904
Trade Name: Glenveigh Vaginal Repair Balloon Catheter
Regulation Number: 21 CFR § 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: KNA
Dated: March 30, 2010
Received: March 31, 2010

Dear Ms. Northcutt:

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.

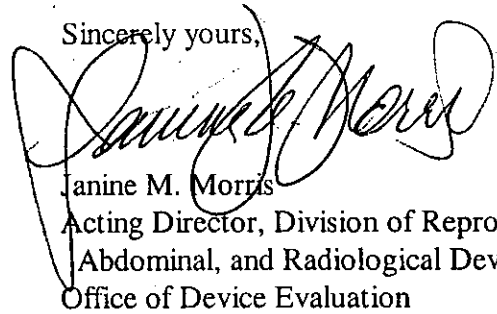
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093904

Device Name: **GLENVEIGH VAGINAL REPAIR BALLOON CATHETER**

Indications For Use:

The Glenveigh Vaginal Repair Balloon is indicated for use during episiotomy/vaginal laceration repair to temporarily prevent the post partum discharge of fluids from the vagina in order to assist with the episiotomy/laceration repair procedure.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K093904

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