MAY - 6 2008 K073493

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PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.93)

Date of Preparation: November 29, 2007

Applicant:	Vygon Corporation 2495 General Armistead Ave. Norristown, PA 19403
Contact Individual:	Courtney Smith, Regulatory Affairs Manager 610-539-9300 Ext. 110
Trade Name:	Hepatostat
Common Name:	Synthetic Absorbable Surgical Suture & Surgical Clamp
Regulation Number:	878.4493 & 878.4493
Product Code:	GAM & GDJ
Classification Name:	Synthetic Absorbable Surgical Suture & Surgical Clamp
Classification:	Class II
Predicate Device Name:	Hepatostat (K061796)
Device Description:	The Hepatostat Set® is an absorbable compression device which allows to perform any type of hepatic resection, large or small, without any significant bleeding. It is made of four pre-perforated absorbable strips. These strips are connected together by twenty Safil® polyfilament ligatures introduced through the liver by a special tubular needle holder. Each suture is terminated by a stainless steel dart and already inserted into a stainless steel tubular needle holder, fitted to the liver thickness. Two clamps enable to bring together two strips.

Intended Use: Hepatostat Set is an absorbable compression system acting as a tourniquet on the hepatic, splenic and nephric tissue. It is used to achieve hemostasis in hepatic, splenic, and nephric resections. It can also be used for traumatic liver, kidney and spleen injuries. It is designed to provide compressive hemostasis to the wound site, and resorb naturally over time after hemostasis has been achieved.

Technology Characteristics: The Hepatostat in this submission is identical to the Hepatostat (K061796). Vygon is resubmitting of premarket notification due to an expanded indication.

Summary of Design Control Activities: Animal testing has been conducted to demonstrate the safety and efficacy for use in splenic and nephric resection.

Conclusion: Performance testing demonstrates that the Hepatostat is substantially equivalent to the predicate devices, and safe and effective to use, when used in accordance with the supplied instructions for use.

Courtney Smith May 5, 2008.

Courtney Smith Date

Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2008

Vygon Corporation
% Ms. Courtney Smith
2495 General Armistead Avenue
Norristown, Pennsylvania 19403-3685

Re: K073493
Trade/Device Name: Hepatostat
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L- lactide) surgical suture
Regulatory Class: II
Product Code: GAM, GDJ
Dated: April 11, 2008
Received: April 14, 2008

Dear Ms. Smith:

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 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): K073493

Device Name: Hepatostat

Indications for Use:

Hepatostat Set is an absorbable compression system acting as a tourniquet on the hepatic, splenic and nephric tissue. It is used to achieve hemostasis in hepatic, splenic, and nephric resections. It can also be used for traumatic liver, kidney and spleen injuries. It is designed to provide compressive hemostasis to the wound site, and resorb naturally over time after hemostasis has been achieved.

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)

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

510(k) Number K073493