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NOV - 2 2006

510K Premarket Notification Submission
Summary of Safety and Efficacy

Date of Preparation: September 22, 2006

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 Set
Common Name:	Absorbable Suture + Liver Clamp
Regulation Number:	878.4493 + 878.4800
Product Code:	GAM
Classification Name:	Synthetic Absorbable Surgical Suture & Surgical Clamp
Classification:	Class II
Predicate Device Name:	Mar-Med Liver Strap (K924223) Safil Synthetic Absorbable Surgical Suture (K031286) MonoSyn Synthetic Absorbable Surgical Suture (K011375) Vicryl Synthetic Absorbable Surgical Suture (K033746)
Device Description:	The Hepatostat Set is an absorbable compression device which was developed for the purpose of hepatic resection, large or small, without any significant bleeding. It consists of four pre-perforated absorbable strips which are sutured together with Safil polyfilament ligatures introduced through the liver with a tubular needle.
Intended Use:	Hepatostat Set is a compression system acting as a tourniquet on the hepatic tissue. It is intended to reduce the risk of bleeding and to achieve hemostasis in hepatic resections (from large to small superficial hepatectomy). It can also be used for traumatic liver injuries.

Technology Characteristics: The Absorbable strips and Safile sutures are broken down by hydrolysis, both copolymers degrade into glycolic and lactic acid which are subsequently metabolized and absorbed by the body. Liver hemostasis is fairly rapid (approximately 15 days) and is not impeded by the reabsorption of the strips and sutures. Complete absorption of the sutures occurs between 60 and 60 days.

Summary of Design Control Activities:

Biocompatibility testing of the material in accordance with ISO 10993-1, including implantation testing at 3, 6, 12 and 15 months demonstrates performance and biocompatibility of the device. In vitro testing demonstrates that the device performance. Sterility testing ensures a sterility assurance level of 10^{-6}.

Conclusion: Biocompatibility and implant testing, performance testing and risk assessment demonstrate that the Hepatostat Set is safe and effective to use, when used in accordance with the supplied instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vygon Corporation
% Regulatory Affairs Associates, LLC
Mr. Stephen Goldner
30833 Northwestern Highway
Suite 121
Farmington Hills, Michigan 48334

NOV - 2 2006

Re: K061796
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: September 30, 2006
Received: October 3, 2006

Dear Mr. Goldner:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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): K061796

Device Name: Hepatostat

Indications For Use:

Hepatostat Set is a compression system acting as a tourniquet on the hepatic tissue. It is intended to reduce the risk of bleeding and to achieve hemostasis in hepatic resections (from large to small superficial hepatectomy). It can also be used for traumatic liver injuries.

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 K061796