K053548

5.0 510(k) SUMMARY

In accordance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

5.1 Submitted By

Protein Polymer Technologies, Inc.
10655 Sorrento Valley Road
San Diego, California 92121
Telephone: (858) 558-6064

Contact: R. Stephen Reitzler
Vice President, Regulatory Affairs & Quality Assurance

Date Prepared: December 19, 2005

5.2 Device Name

Trade or Proprietary Names:	Modified *Pva-Plus*™ Foam Embolization Particles Modified *MaxiStat*™ Pva Foam Embolization Particles Modified *MicroStat*™ Pva Foam Embolization Particles
Common or Usual Name:	Polyvinyl alcohol (Pva) foam embolization particles
Classification Name:	Neurovascular embolization device

5.3 Predicate Devices

The subject devices are substantially equivalent to the following predicate devices:

- *Pva-Plus*™ Foam Embolization Particles (Surgica Corp.; K001678)
- *MaxiStat*™ Pva Foam Embolization Particles (Surgica Corp.; K020033)
- *MicroStat*™ Pva Foam Embolization Particles (Surgica Corp.; K032619)

5.4 Device Description

The subject devices are particles of nonabsorbable synthetic polyvinyl alcohol (Pva) foam. The devices do not contain any colorant or other additive, and are uncoated. Each is offered in a range of particle sizes, from which the clinician may select the particle size most appropriate for the desired effect and targeted vasculature. The devices are intended to be delivered to the selected anatomical site by means of a syringe, through an infusion catheter of appropriate diameter. The devices are provided sterile, non-pyrogenic, and are intended for single-use.

5.5 Intended Use

Modified *Pva-Plus*™, Modified *MaxiStat*™, and Modified *MicroStat*™ Pva Foam Embolization Particles may be used for vascular occlusion of blood vessels within the neurovascular system. They are intended for use in the endovascular management of arteriovenous malformations (AVMs) and neoplastic lesions when presurgical devascularization is desirable.

5.6 Comparison to Predicate Devices

The subject devices differ from the predicate devices only in packaging configuration. The primary unit package form has been modified from that of the predicates to facilitate ease of use by the clinician, and the modification does not alter essential device design characteristics or indications for use. Specifically, the primary unit package has been changed from a sealed glass vial to a thermoformed blister with peel-off TYVEK® lid, and now includes the hydration/delivery syringe(s) necessary for administration of the devices. With respect to material composition, particle configuration and range of sizes offered, manufacturing, biocompatibility, how supplied, indications, and method of use, the subject devices are unchanged from the predicate devices.

5.7 Summary of Non-Clinical Tests

In that the modification that is the basis for this 510(k) submission impacts only the unit package configuration, non-clinical testing is restricted to that which verifies or validates sterility, and shelf life. All such tests conform to recognized standards.

5.8 Summary of Clinical Tests

(Not applicable)

5.9 Conclusions of Non-Clinical and Clinical Tests

The results of all testing demonstrated the substantial equivalence of the subject devices to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 2006

Mr. R. Stephen Reitzler
Vice President, Regulatory Affairs and Quality Assurance
Protein Polymer Technologies, Inc.
10655 Sorrento Valley Road
San Diego, California 92121

Re: K053548
Trade/Device Names: Modified *Pva-Plus*™ Foam Embolization Particles, Modified *MaxiStat*™ Pva Foam Embolization Particles, and Modified *MicroStat*™ Foam Embolization Particles
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: II
Product Code: HCG
Dated: December 19, 2005
Received: December 21, 2005

Dear Mr. Reitzler:

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.

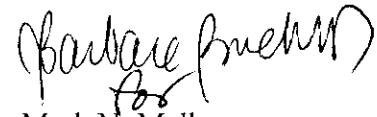
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting 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 Names: Modified *Pva-Plus*™ Foam Embolization Particles;
Modified *MaxiStat*™ Pva Foam Embolization Particles; and
Modified *MicroStat*™ Pva Foam Embolization Particles

Indications for Use:

PVA particles may be used for vascular occlusion of blood vessels within the neurovascular systems. They are intended for use in the endovascular management of arteriovenous malformations (AVMs) and neoplastic lesions when presurgical devascularization is desirable.

Prescription Use _______
(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)

Barbara Buehler for MXM

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

510(k) Number K053548