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:

SEP 19 2006

5.1 Submitted By

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

Contact: Radine Ganz Pobuda, RAC
Director, Quality Systems & Regulatory Affairs

Date Prepared: May 5, 2006

5.2 Device Name

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

5.3 Predicate Devices

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

- *PVA Plus*™ Foam Embolization Particles (PPTI; K053548)
- *MaxiStat*™ PVA Foam Embolization Particles (PPTI; K053548)
- *MicroStat*™ PVA Foam Embolization Particles (PPTI; K053548)
- *Contour SE*™ Microspheres (Boston Scientific; K034068)
- *Contour® Emboli* PVA (Boston Scientific; K030966)
- *Embosphere®* Microspheres (Biosphere Medical; K021397)

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 delivered to the selected vascular location by means of a syringe, through an infusion catheter of diameter appropriate for the selected particle size. The subject devices are manufactured for PPTI by Surgica Corporation, 5090 Robert J. Matthews Parkway, No. 4, El Dorado Hills, CA 95762.

5.5 Intended Use

PVA Plus™, *MaxiStat*™, and *MicroStat*™ PVA Foam Embolization Particles may be used for vascular occlusion of blood vessels within the neurovascular and peripheral vascular system. They are intended for arterial embolization of arteriovenous malformations (AVMs) and hypervascular tumors in the peripheral vasculature, and for vascular occlusion of blood vessels within the neurovascular system for the embolization of AVMs and neoplastic lesions.

5.6 Comparison to Predicate Devices

The subject devices *do not differ in any regard* from PPTI's predicate *PVA Plus*™, *MaxiStat*™, and *MicroStat*™ devices currently cleared for market in the U.S. Further, the subject devices are substantially equivalent to other predicate devices cleared for commercial distribution in the U.S., in terms of material composition, particle configuration, range of sizes offered, biocompatibility, packaging, how supplied, indications, and method of use. Among these predicates are the *Contour*® Emboli PVA and *Contour SE*™ Microsphere devices marketed by Boston Scientific (K030966 and K034068, respectively), and *Embosphere*® Microspheres, marketed by Biosphere Medical (K021397).

5.7 Summary of Non-Clinical Tests

Nonclinical tests, both *in vitro* and *in vivo*, have demonstrated the substantial equivalence of the subject devices to commercially-available predicates in terms of performance.

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

Protein Polymer Technologies, Inc.
% Radine Pobuda, RAC
Director, Quality Systems and
Regulatory Affairs
10655 Sorrento Valley Road
San Diego, California 92121

SEP 19 2006

Re: K061790
Trade/Device Name: *PVA Plus*™ Foam Embolization Pareticles; *MaxiStat*™ PVA Foam Embolization Particles: and *MicroStat*™ PVA Foam Embolization Particles
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular embolization device
Regulatory Class: II
Product Code: KRD, HCG
Dated: June 23, 2006
Received: June 26, 2006

Dear Radine Pobuda:

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,

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): K061790

Device Names: *PVA Plus*™ Foam Embolization Particles;
MaxiStat™ PVA Foam Embolization Particles; and
MicroStat™ PVA Foam Embolization Particles

Indications for Use:

PVA particles are indicated for arterial embolization of arteriovenous malformations (AVMs) and hypervascular tumors in the peripheral vasculature, and for vascular occlusion of blood vessels within the neurovascular system for the embolization of AVMs and neoplastic lesions.

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)

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

510(k) Number K061790