SUMMARY OF SAFETY AND EFFECTIVENESS

I. GENERAL INFORMATION

Device Generic Name: Absorbable Surgical Hemostatic Agent

Device Trade Name: Arista™ AH Absorbable Hemostat

Applicant's Name and Address: Medafor, Inc.
2700 Freeway Boulevard, Suite 800
Minneapolis, Minnesota 55430

Date of Panel Recommendation: None

Premarket Approval Application Number: P050038

Date of Notice of Approval to Applicant: September 26, 2006

II. INDICATIONS FOR USE

Arista™ AH Absorbable Hemostat (hereinafter called Arista AH) is indicated in surgical procedures (except neurological, ophthalmic, and urological) as an adjunctive hemostatic device to assist when control of capillary, venous, and arteriolar bleeding by pressure, ligature, and other conventional procedures is ineffective or impractical.

III. CONTRAINDICATIONS

Do not inject or place Arista AH into blood vessels as potential for embolization and death may exist.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Arista AH labeling.

V. DEVICE DESCRIPTION

Arista AH is a sterile, absorbable hemostatic agent. It consists of Microporous Polysaccharide Hemospheres (MPH®). MPH is Medafor's trademarked name for the water-insoluble, hydrophilic, microporous polysaccharide particles prepared from purified plant starch. Arista AH is provided in medical grade polyethylene applicator/containers. Arista AH is designed to be either directly applied onto the wound site directly from the applicator/container or it may be used in conjunction with Medafor's commercially available applicators.

VI. ALTERNATE PRACTICES AND PROCEDURES

Conventional procedures used to control bleeding include the use of direct pressure, sutures, and/or electrocautery. In addition, absorbable hemostatic agents such as oxidized cellulose, collagen, and gelatin sponge or powder are commercially available. Thrombin may also be used alone for hemostasis or may be used in conjunction with gelatin hemostatic agents.

VII. MARKETING HISTORY

Arista AH has been marketed in the European Union since August 2002, in Canada since October 2002, and in Australia since June 2004. It is also commercially available in the following countries:

Argentina	Australia	Austria
Belgium	Brazil	Canada
Czech Republic	Denmark	England
Finland	France	Germany
Greece	Hong Kong	Hungary
Israel	Italy	Netherlands
New Zealand	Norway	Peru
P.R. China	Poland	Portugal
Romania	San Marino	Saudi Arabia
Scotland	Singapore	Slovakia
South Africa	Spain	Sweden
Switzerland	Turkey	

Arista AH has not been withdrawn from marketing for any reason related to the safety and effectiveness of the device.

VIII. POTENTIAL ADVERSE EVENTS

Adverse Events Noted During Arista AH Trial:

In a randomized prospective, concurrently controlled clinical trial, a total of 288 randomized patients received Arista AH or the Control (Gelatin Sponge with or without thrombin). The most common recorded adverse events recorded were pain related to surgery, anemia, nausea, and lab values out of normal range. The following is a complete list of adverse events reported in greater than 5% of the Arista AH treated patients. The corresponding adverse events for the Control group are listed for comparison. None of the adverse events that occurred were judged by either the investigator or the Data Safety Monitoring Board to be related to the use of Arista AH or the control.

Adverse Event	Adverse Events Reported in Greater than 5% of the Arista Treated Patients	
	Arista AH	Control
Pain related to surgery	140 (96.6%)	139 (97.2%)
Anemia	52 (35.9%)	49 (34.3%)
Nausea	44 (30.3%)	39 (27.3%)
Constipation	27 (18.6%)	12 (8.4%)
Lab values out of normal range	26 (17.9%)	20 (14.0%)
Arrhythmia	24 (16.6%)	31 (21.7%)
Respiratory Dysfunction	19 (13.1%)	18 (12.6%)
Hypotension	18 (12.4%)	18 (12.6%)
Ecchymosis	13 (9.0%)	8 (5.6%)
Fever	12 (8.3%)	15 (10.5%)
Pruritis	11 (7.6%)	12 (8.4%)
Tachycardia	10 (6.9%)	10 (7.0%)
Edema	9 (6.2%)	9 (6.3%)
Pain unrelated to surgery	9 (6.2%)	8 (5.6%)
Hemorrhage	9 (6.2%)	7 (4.9%)
Hypertension	8 (5.5%)	7 (4.9%)

Other adverse events reported in fewer than 5% of the Arista AH population included: Parethesia, Cutaneous Bleed, Infection, Seroma, Confusion, Renal Insufficiency, Heartburn, Diarrhea, Vertigo, Hypovolemia, Pneumonia, Pleural Effusion, Paresis, Dermal Irritation, Urinary Dysfunction, Muscle Spasms, Hematuria, Ileus, Coagulopathy, Pneumothorax, Dysphagia, Ischemia, Deep Vein Thrombosis, Gout, Inflammation, Necrosis, Hematoma, Hypothermia, Agitation, Rash, Hypoxaemia, Myocardial Infarction, Hyperthermia, Hypercapnia, Clostridium Difficile, Eye Irritation, Xerostomia, Nerve Palsy, Pericardial Effusion, Cardiac Tamponade, Excoriation, Fatigue, Flatus, Unrelated Illness, Cellulitis, Syncope, Shivering, Sore Throat, Alcalosis, Heel Ulcer, Anastomotic Leak, Clot, Gastritis, Left Ventricular Fistula, Liver Insufficiency, Adrenal Insufficiency.

Adverse Reactions that have been Attributed to Other Absorbable Hemostatic Agents:

Note that Arista AH is a unique absorbable hemostatic agent consisting of 100% purified plant starch and it exhibits a faster absorption time (approximately 24 to 48 hours) compared to other absorbable hemostatic agents that absorb in 3 to 8 weeks. The following adverse events have been reported for other absorbable hemostatic agents and may apply to the use of Arista AH:

- Paralysis and nerve damage have been reported when hemostatic agents are used in or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm. While most of these reports have been in connection with laminectomy, reports of paralysis have also been received in connection with other procedures.

- Compression of the brain and spinal cord resulting form the accumulation of sterile fluid has been observed.

IX. SUMMARY OF PRECLINICAL STUDIES

Biocompatibility: Per International Standards Organization (ISO) Standard ISO10993-1 *Biological Evaluation of Medical Devices: Evaluation and Testing* and FDA Blue-Book Memorandum G95-1 *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"*, Arista AH is an implant device used on bone/tissue with a prolonged duration. Medafor performed all testing required by both documents and conducted supplementary testing. Testing results are summarized below:

Test	**Protocol Description**	**Results**
Cytotoxicity	ISO Minimum Essential Medium Elution Using L-929 Mouse Fibroblast Cells	Non-toxic
Sensitization	ISO Guinea Pig Maximization Sensitization Test	0% Sensitization
Irritation	ISO Intracutaneous Reactivity Test	Non-irritant
Irritation	ISO Vaginal Mucosal Irritation Test	Non- irritant
Systemic Toxicity	ISO Acute Systemic Injection Test	Non-toxic
Sub-chronic Toxicity	Sub chronic (14-Day) Intravenous Toxicity Study	Non-toxic
Implantation	ISO Intramuscular Implant Test, 7 and 28 Day Duration in rabbits	Non-irritant
Hemocompatability	Hemolysis Test Extract Method	Non-hemolytic
Genotoxicity	In Vitro Genotoxicology: Bacterial Mutagenicity Test-Ames Assay	Non-mutagenic
Genotoxicity	In Vitro Genotoxicology: Mouse Lymphoma Assay	Non-mutagenic
Genotoxicity	In Vitro Genotoxicology: Mouse Micronucleus Assay	Non-mutagenic
Pyrogenicity	Materials Mediated Rabbit Pyrogen Test	Non-pyrogenic

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Preclinical Safety and Effectiveness Testing:

Thromboelastography (TEG) analysis of Arista AH added to blood: Clotting time of re-calcified whole blood was measured by TEG with and without the addition of Arista AH. A significant decrease was noted in the time required for clot formation for samples with added Arista AH. The Arista AH-treated blood quickly gelled and fibrin formation began within 2 to 4 minutes vs. 7 to 10 minutes for controls (no addition of Arista AH). The addition of Arista AH was observed to accelerate clot formation.

Scanning Electron Microscopy (SEM) analysis of Arista AH added to blood: SEM photos of Arista AH added to human blood showed a high concentration of red blood cells and platelets at the wound/Arista AH interface due to the Arista AH particles drawing in the fluid components of the blood. The dense, tight packing of red blood cells and platelets seen in the photos provides visual evidence of the concentrating and gel forming properties of Arista AH involved in clot formation.

Use of Arista AH with Intraoperative Cell Salvage Circuits: In order to assess the safety of Arista AH during autotransfusion, studies were conducted to determine how much Arista AH passes through a typical cell salvage device under various filtering conditions. The experiments demonstrate that conventional cell salvage equipment fitted with 40 µm filters will remove approximately 99.47% of the introduced Arista AH from salvaged blood.

Seven day tissue resorption studies of implanted Arista AH in a porcine model: There was no detectable Arista AH residue in tissue samples obtained seven days after implantation of Arista AH into liver, kidney, skin and abdominal aorta sites.

Evaluation of the degradation and absorption of Arista AH beads in a mouse model: Saline-swollen Arista AH beads applied through subcutaneous injections in a mouse model begin to degrade within 15 minutes with no evidence of residual material after 30 minutes.

Bone healing response study on 24 rabbits with 4 and 7 week follow-up: Arista AH, bone wax and an approved collagen hemostatic device were applied to bony defects in rabbits in order to determine their effect on bone healing when assessed by visual scoring, pathologic examination, and bone growth measures. Arista AH-treated defects had better bone growth that defects treated with either bone wax or collagen hemostat, but worse bone growth that untreated defects.

Severe bleeding model on femoral artery and vein in rabbits: The ability of Arista AH to induce hemostasis in arterial and venous lesions created in the arteries and veins of rabbits was studied. In a contra-lateral model, 83% and 92% of all arterial and venous lesions treated with Arista AH achieved improved hemostasis following 60 and 90 seconds of pressure applied with gauze. This is

contrasted to 25% and 33% of the arterial and venous lesions, which achieved improved hemostasis when treated with the control treatment of gauze and pressure alone after 60 and 90 seconds.

***Hemostatic effectiveness of Arista AH in a porcine punch liver biopsy model*:** Punch liver biopsies were made in pig livers in order to evaluate the effectiveness of Arista AH compared to a commercially available porcine gelatin sponge in aiding hemostasis of actively bleeding 6 mm wounds. Within 5 minutes of application of the hemostatic agent, 89% of Arista AH-treated sites and 50% of gelatin sponge-treated sites achieved complete hemostasis. Within 10 minutes, 100% of Arista AH-treated sites and 96% of gelatin sponge-treated sites achieved complete hemostasis. Time to hemostasis was calculated as 155 ± 112 s for Arista AH and 322 ± 137 for the gelatin sponge.

***Inhalation of Arista AH in a pig model*:** Evans Blue stained Arista AH was introduced into the trachea or the right main bronchi of pigs. No adverse effect on lung function was noted. Measurements at 1 hour, 48 hours and 168 hours indicated that all Arista AH was either removed from the lungs by the mucous membrane or completely degraded by 48 hours as it was only detectable at 1 hour.

***The effect of Arista AH on abdominal infection in a rat model*:** In an *in vivo* rat infection model, a specified amount of *E. coli* was inoculated into an induced abdominal wound followed by treatment with no hemostatic agent (control), an absorbable gelatin sponge (control device) and Arista AH. After 72 hours, animals were sacrificed and culture of the removed tissue found that there is no statistically significant increase in the rate of *E. coli* infection in wounds treated with Arista AH (an average of 6.9×10^5 colony forming units [CFU] found after 72 hours) compared to the rate in wounds treated with control (average of 3×10^5 CFU after 72 hour) indicating that Arista AH does not act as a nidus for infection. The rate of infection in wounds treated with the device control (average of 2.4×10^7 CFU after 72 hours) was found to be statistically greater than both the control and Arista AH. Under the conditions of the model, a wound is considered infected if the CFU/g exceeded 10^5. For the control arm, 14% of the wounds were infected versus 24% for Arista AH ($p= 0.34$) which is not significantly different. A comparison of the control versus the device control showed a significant difference between the infection rates (14% for control and 87% for device control, $p=0.00003$). These effects for bacteria besides *E. coli* cannot be predicated and the clinical effects are not known.

***The use of Arista AH to control bleeding in a partial nephrectomy pig model*:** The effectiveness of Arista AH in controlling bleeding during a partial nephrectomy while using a suction applicator (a prototype MVac vacuum applicator system) was compared to a control group using ligation, electrocautery and a resorbable hemostatic agent manufactured from regenerated oxidized cellulose that is considered a standard of care. For Arista AH, average time to hemostasis was 4.67 ± 0.8 minutes and average ischemic time (time from vessel

occlusion to removal of clamp) was 2.67 ± 0.68 minutes. For the control, average time to hemostasis was 7.75 ± 1.29 minutes and average ischemic time was 8.33 ± 0.75 minutes. The results of this study may not directly correlate with clinical outcomes of use of Arista AH in these applications and clinical outcomes cannot be predicted.

***Laparoscopic approach for partial nephrectomy in pigs using Arista AH for bleeding control*:** The ability of Arista AH to induce hemostasis in a laparoscopic approach to a partial nephrectomy in a pig model was studied. Arista AH was applied laparoscopically through a prototype laparoscopic applicator attached to the bellows containing the Arista AH. Hemostasis was achieved in all cased, although some required multiple applications. The results of this study may not directly correlate with clinical outcomes of use of Arista AH in these applications and clinical outcomes cannot be predicted.

***Degradation of Arista AH in pig liver and skin lesions*:** The time range for the degradation of Arista AH in blood clots on liver and skin wound sites was determined in a porcine model. Animals were sacrificed at 4, 5, 6, 8, 10, 12, 16 & 24 hours after treatment. Gross inspection of wound sites found complete degradation of Arista AH on the liver at 6 hours and on skin at 16 hours. Histopathological examination found Arista AH in approximately 50% of 6 hour liver lesions and 50% of 16 hour skin lesions. The histopathology was used as the definitive test for residual Arista AH and the best fit to the data indicated that Arista AH was removed within 16 hours in pig liver and 28 hours in pig skin. The tests confirm that Arista AH is cleared from tissues at rates that depend upon the local conditions and that the particles are typically absorbed within 24 to 48 hours. Collagen-based hemostats have been observed to absorb in 6 to 8 weeks after application and oxidized cellulose products normally require 3 to 4 weeks. The duration of the clots formed in the presence and absence of Arista AH was not examined in this study.

Safety, Effectiveness and biodegradation of Arista AH in a rat brain implantation model: Phase I: The safety and degradation of Arista AH was assessed in a rat brain implantation model. Arista AH was compared to commercially available control hemostatic agents, indicated for neurosurgical use (microfibrillar collagen, gelatin matrix/thrombin combination, oxidized cellulose). At each time point (3, 7, or 28 days), tissue treated with the control agents exhibited residual material in 50% or more of the animals. Observations at 28 days with the control agents indicated the residue had stimulated an early granulomatous reaction. In all cases (3, 7, and 28 days), the Arista AH-treated brains had histological changes similar to those observed in the negative control (no hemostatic agent), i.e. macrophages infiltrating the surgical regions with no evidence of foreign body reaction or granuloma formation. In addition, no residual Arista AH was detected at any time point.

Phase II: In order to evaluate the effectiveness of Arista AH, this study compared Arista AH to the control agents identified above. All treated lesions achieved hemostasis within 3 minutes while the negative control lesions did not. Following the achievement of hemostasis, the animal was sutured and survived according to protocol. At each time point (3, 7, or 14 days), tissue treated with the control hemostatic agents exhibited residual material in 100% of the animals. Observations at 7 and 14 days for the gelatin /thrombin combination and at 14 days for the oxidized cellulose groups indicated the presence of foreign body reaction in 67% and 100% of the group, respectively. At all time points (3, 7, and 28 days plus 6 and 12 hours, the Arista AH-treated brains had histological changes similar to those observed in the negative control and no residual Arista AH was present at any time point. The results of this study may not directly correlate with clinical outcomes of use of Arista AH in these applications and clinical outcomes cannot be predicted.

***Ocular irritation testing in rabbits*:** In order to assess the safety of Arista AH in ocular applications, ocular irritation was assessed after Arista AH was instilled into the eyes of rabbits. Introduction of 100 mg of Arista AH into the eye was found to be minimally irritating. The results of this study may not directly correlate with clinical outcomes of use of Arista AH in these applications and clinical outcomes cannot be predicted.

***Wound healing effects in porcine skin grafts*:** The purpose of the study was to determine the effectiveness of Arista AH in controlling bleeding at graft sites and to examine the effects on subsequent healing following application to the interface between the wound bed and the skin graft. Arista AH was compared to standard skin graft hemostatic therapy of spraying the site with topical thrombin. Animals were survived from 7 to 10 days. After sacrifice, tissue samples were harvested and slides prepared for histopathological examination. No Arista AH was detected at any of the five treated sites in animals, and the medical pathologist could not detect any significant histopathological differences in the healing response between the Arista AH and standard thrombin treatment. The results of this study may not directly correlate with clinical outcomes of use of Arista AH in these applications and clinical outcomes cannot be predicted.

X. SUMMARY OF CLINICAL STUDIES

Study Design and Objectives:

A prospective, multi-center, multi-specialty, randomized, non-inferiority, controlled clinical trial was conducted. Two hundred eighty-eight (288) patients were randomized and treated at nine investigational centers. The objective of the study was to evaluate the safety and effectiveness of Arista AH versus a commercially available absorbable gelatin sponge used with or without thrombin to control intraoperative bleeding in orthopedic, general, and cardiac surgeries. The use of thrombin in conjunction with the control was at physician discretion.

Thrombin was used in 12 of 143 control subjects; the percentage of subjects achieving hemostasis of the first treated lesion within protocol specified time limits and the mean time to hemostasis were not statistically different between control subjects treated with and without thrombin.

Patients were randomized only after a lesion suitable for treatment with an adjunctive hemostatic device was identified. The subjects may have received various forms of peri-procedural anti-coagulation prior to randomization and treatment. However, the protocol did not require an assessment of coagulation status at the time of treatment. Therefore the subject's ability to coagulate at time of device application is unknown. Complete hemostasis was defined as cessation of bleeding. The primary endpoint was complete hemostasis of the first treated lesion within 5 minutes (3 minutes for cardiac). Although multiple lesions in the same patient could be treated per the protocol, only the first treated lesion was used to determine the effectiveness as this was the only lesion that was truly randomized.

Primary Endpoint

For the primary endpoint, complete hemostasis of the first treated lesion within 5 minutes (3 minutes for cardiac), was achieved in 90.3% of the randomized and treated subjects in the Arista AH group and in 80.4% of the randomized and treated subjects in the control group. Arista AH was demonstrated to be non-inferior to the control ($p<0.0001$). The upper 95% limit on the difference in proportions (Control – Arista) was less than zero (-2.4%).

Primary endpoint data for the entire randomized and treated patient population as well as stratified by surgical specialty are summarized in the table below:

Complete Hemostasis of First Treated Lesion within 5 Minutes (3 for Cardiac)		
Primary Efficacy Endpoint	**Arista AH n/N (%)**	**Control n/N (%)**
Hemostasis of First Treated Lesion	131/145 (90.3%)	115/143 (80.4%)
Surgical Application	**Arista AH n/N (%)**	**Control n/N (%)**
General (within 5 minutes)	68/72 (94.4%)	56/72 (77.8%)
Orthopedic (within 5 minutes)	33/35 (94.3%)	32/37 (86.5%)
Cardiac (within 3 minutes)	30/38 (78.9%)	27/34 (79.4%)

Secondary Endpoint

A secondary endpoint was time to hemostasis for the first treated lesion. The data for time to hemostasis are summarized below. The times to achieve complete hemostasis for the Arista AH and Control groups were statistically different using the chi square test (p=0.003).

Cumulative Percent of Patients with Complete Hemostasis– First Treated Lesion:

Time to Complete Hemostasis	**Arista AH** n (%)	**Control** n (%)
1 minute	73/145 (50.3%)	47/143 (32.9%)
2 minutes	96/145 (66.2%)	83/143 (58.0%)
3 minutes (Cardiac to 3 minutes only)	124/145 (85.5%)	103/143 (72.0%)
4 minutes	130/145 (89.6%)	111/143 (77.6%)
5 minutes	131/145 (90.3%)	115/143 (80.4%)

When data are stratified by surgical specialty, the median times to hemostasis were shorter for the Arista AH group than for the Control group. The median times are summarized in the table below. The median time to hemostasis for the Arista AH Arm was statistically different from the Control arm using the non-parametric Wilcoxon sign-rank test (p=0.002). Note that one individual in the cardiac group required 56.8 minutes to achieve hemostasis and is considered an outlier.

Comparison of Time to Hemostasis – First Treated Lesion

	Arista AH Median (n) (min, max)	**Control** Median (n) (min, max)
Median Time to Hemostasis (minutes)	1.0 (144) (1.0, 56.8)	2.0 (143) (1.0, 19.2)
General	2.0 (72) (1.0, 19.5)	2.0 (72) (1.0, 15.0)
Cardiac	2.0 (38) (1.0, 56.8)	3.5 (34) (1, 19.2)
Orthopedic	1.0 (34) (1.0, 6.2)	2.0 (37) (1.0, 7.0)

Additional Information

In the ARISTA trial, subjects in the ARISTA arm could have up to five (5) bleeding lesions treated with Arista AH. In the trial, surgeons used between approximately 1 to 9 g to treat these lesions. In the Arista Trial, the mean number of product applications onto the first treated lesion was 1.4 (range 1 to 5) and for control, the mean number of product applications was 1.4 (range 1 to 5).

In the ARISTA Trial, the protocol allowed for the treatment of lesions that did not achieve hemostasis within the protocol specified timeframes (5 minutes, 3 minutes for cardiac) with any method necessary including commercially available hemostatic agents. The following table presents information on the method of and time range for achieving hemostasis in these cases.

Treatment Group	**ARISTA AH**		**Control**	
Method Used to Control Bleeding in Hemostasis Failures	**N**	**Time range to hemostasis**	**N**	**Time range to hemostasis**
Commercially Available Hemostat (fibrillar, gelatin sponge)	5	3.7 to 56 min	5	5 to 19 min
Sutures	4	4.4 to 7 min	11	3.8 to 9.9 min
Electrocautery	3	5.3 to 14 min	10	4.3 to 7 min
Pressure	1	3.2 min	1	15 min
Observe	1	NA	-	-
Suture and commercially available hemostat	-	-	1	14.9 min

XI. CONCLUSIONS DRAWN FROM STUDIES

Risk Benefit Analysis

The absence of adverse events related to the use of Arista AH combined with the hemostatic effectiveness of Arista AH attest to the acceptable risk/benefit ratio of Arista AH in controlling capillary, venous, and arteriolar bleeding. Therefore, it is reasonable to conclude that the benefits of use of the device for the target population outweigh the risk of illness or injury when used as indicated in accordance with the directions for use.

Safety

The results of the preclinical and clinical testing demonstrated that there is reasonable assurance of safety for Arista AH for the stated indication for use. Preclinical testing demonstrated that the purified plant starch used to manufacture Arista AH is non-immunogenic, biocompatible, well tolerated and readily absorbed in tissue. The absence of adverse events related to the use of Arista AH in the clinical trial supports the safety of Arista AH as an adjunctive hemostatic agent.

Effectiveness

The results of the preclinical and clinical testing demonstrated that there is reasonable assurance of effectiveness for Arista AH for the stated indication for use. Preclinical testing demonstrated that Arista AH is fully absorbed by the body in approximately 24 to 48 hours, is biocompatible, and is hemostatic. Medafor, Inc. performed a prospective, multi-center, multi-specialty, randomized, non-inferiority, controlled clinical trial designed to compare the hemostatic ability of Arista AH versus a control of commercially available absorbable gelatin sponge. Complete hemostasis of the first treated lesion within 5 minutes (3 minutes for cardiac), was achieved in 90.3% of the randomized and treated subjects in the Arista AH group and in 80.4% of the randomized and treated subjects in the control group. Arista AH was demonstrated to be non-inferior to the control ($p<0.0001$). The upper 95% limit on the difference in proportions (Control – Arista AH) was less than zero (-2.4%).

XII. PANEL RECOMMENDATION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the General and Plastic Surgery Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CDRH DECISION

FDA issued an approval order on September 26, 2006.

The applicant's manufacturing facilities were inspected and were found to be in compliance with the Quality System Regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for Use: See the labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Reactions in the labeling.

Postapproval Requirements and Restrictions: See approval order.