K003992

JUN - 1 2001

510(k) Summary

Submitter Information:

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Trade Name: PercuSurge GuardWire Temporary Occlusion and Aspiration System

Common Name: Distal Occlusion Balloon Catheter

Classification Name: (Approx.)
-Catheter, Intravascular Occluding, Temporary
-Percutaneous Catheter
-Guide Wire

Premarket Notification Number: K003992

Predicate Device: N.A.

Date Prepared: December 20, 2001

Date Updated: May 25, 2001

Description

The PercuSurge GuardWire Plus Temporary Occlusion & Aspiration System provides temporary vascular occlusion during diagnostic and interventional procedures in the coronary vasculature, specifically-diseased coronary bypass grafts. It is comprised of four principal components: the GuardWire Temporary Occlusion Catheter, the MicroSeal Adapter, the EZ Flator Inflation Device and the Export Aspiration Catheter.

The GuardWire Plus System is a sterile, single use disposable device, packaged in a protective polyethylene tray covered by a polyethylene/Tyvek pouch. The pouch is then placed into a chipboard carton for protection during shipment. Both the pouch and the carton are labeled for easy product recognition.

The GuardWire Plus System is available in the following configurations:

Table 1: GuardWire Plus Configurations

Catalog Number	Wire Diameter	Wire Length	Balloon Range
G14-6-200 IDE	0.014"	200cm	3.0 – 6.0mm
G14-6-300 IDE	0.014"	300cm	3.0 – 6.0mm

The GuardWire Plus Temporary Occlusion Catheter is a 0.014" diameter guidewire available in lengths of 200 and 300 centimeters. The industry standard 0.014" diameter of this device allows for the delivery of a wide range of diagnostic and interventional devices over its shaft. The shaft is coated with Teflon to limit the frictional forces encountered when passing therapy devices over the wire. The distal end of the GuardWire contains an inflatable elastomeric balloon designed to occlude the target vessel during emboli-causing procedures such as stenting or angioplasty. The balloon is fully compliant and exerts less than two atmospheres of pressure on the target vessel during occlusion. The GuardWire's occlusion balloon can accommodate vessel sizes ranging from 3mm to 6mm in diameter. The distal tip of the wire is a shapeable radiopaque platinum coil similar to other standard guidewires.

The GuardWire is used in conjunction with a removable adapter that assists in the inflation and deflation of the distal occlusion balloon. The MicroSeal Adapter provides a means for opening and closing the internal MicroSeal of the GuardWire which is a small valve internal to the GuardWire Plus Temporary Occlusion Catheter. When the MicroSeal Adapter is in the "OPEN" position, the GuardWire internal seal is opened. This establishes fluid access to the occlusion balloon through the hollow Nitinol GuardWire shaft. When the MicroSeal Adapter is in the "CLOSE MICROSEAL" position, the MicroSeal of the GuardWire closes. This discontinues fluid access to the occlusion balloon. This allows the occlusion balloon of the GuardWire to remain inflated in the absence of direct communication with an inflation device.

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GuardWire Plus catheter

The proximal end of the GuardWire Plus catheter is able to control the flow of contrast fluid when used in conjunction with the MicroSeal Adapter. This is achieved by means of a micro-seal plug located on the proximal end of the GuardWire Plus catheter. The MicroSeal plug consists of a stainless steel wire that is formed to provide friction in the hypo-tube with a sealing member on the distal end. The plug is pushed in and out, hence the sealing member moves distal and proximal to the inflation port, via the MicroSeal Adapter pads that grip the wire plug and are moved in conjunction with the Adapter knob. An inflation port is positioned on the hypotube to line up with the inflation port on the Adapter to provide a continuous fluid path to inflate the occlusion balloon. Fluid is transferred from the EZ Flator to the Adapter through the hypo-tube to fill the occlusion balloon. Fluid, i.e., diluted contrast, passes through the distal end and into the elastomeric occlusion balloon via the laser coil.

EZ Flator Inflation Device

The EZ Flator is a controlled volume syringe system contained in a single housing that enables the exact amount of diluted contrast to fill the occlusion balloon to the appropriate size. The fluid is pushed through the extension tubing via a steel plunger pin that is controlled by the inflation dial. Once the hypo-tube is prepped and the pin is pushed past the distal o-ring, a seal is formed in the extension line. The volume of the plunger pin in the inflation syringe barrel distal to the distal o-ring equates to the volume of the balloon. Therefore, inflation of the balloon is achieved by turning the dial, which pushes the plunger pin forward, to the appropriate volume indicated on the dial pad.

The deflation syringe barrel is used for prepping the hypo-tube and deflating the occlusion balloon. A handle is attached to the plunger to provide a vacuum to the deflation syringe barrel. The deflation syringe barrel is used only when the inflation dial is in the "0" position, i.e., when the plunger pin is positioned proximal to the distal o-ring, as shown below, thereby opening the fluid path. In the drawing below the housing and plunger handle are not shown.

Export Aspiration catheter

The Export Aspiration catheter is a dual lumen catheter. The smaller of the lumens is the wire lumen used to run over the GuardWire. The size of the wire lumen is sized so that the Export catheter may run over the GuardWire smoothly. The larger sized lumen is the aspiration lumen. Via the 20cc syringe and one-way stopcock attached to the proximal end of the Export, blood and debris is evacuated from the graft and into the syringe.

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MicroSeal Adapter

The MicroSeal Adapter provides the mechanism to move the plug on the GuardWire catheter. Six grip pads are located on the Adapter, three on the upper half and three on the lower. Three wire clips are found on the lower half and are used for holding the wire firmly between the pads. The proximal pads are movable via the Adapter knob. The other four pads are immovable and are used to hold in place the GuardWire distal to the plug. Once the wire is placed in the Adapter and the knob is moved to the open position, the proximal pads slide, opening the plug. Diluted contrast flows through the Adapter via the inflation port. This port is sealed when the Adapter is closed and is lined up with the inflation port on the GuardWire when placed in the Adapter.

Statement of Indications for Use

The PercuSurge GuardWire Plus Temporary Occlusion & Aspiration System is indicated for use in the coronary saphenous vein bypass grafts to:

- Contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures.
- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.
- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.

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Technological Characteristics

Table 2: Comparison Chart

Comparison Feature:	**TOBC:** GuardWire® System	**GuardWire Temporary Occlusion and Aspiration System:** GuardWire® Plus System
System Description:	The PercuSurge® GuardWire® Temporary Occlusion Balloon (TOB) System is comprised of three principal components: the GuardWire® Temporary Occlusion Catheter, the MicroSeal™ Adapter and the Export® Aspiration Catheter. The GuardWire® Temporary Occlusion Catheter has a diameter that is similar to commonly used .014" guide wires in lengths of 200 and 300 cm and has a distal elastomeric balloon. The small profile of this device allows for the delivery of a wide range of diagnostic and interventional devices over its shaft. The GuardWire® is offered in four vessel size ranges accommodating vessel diameters from 3.0mm to 5.0mm. For each vessel size, PercuSurge® provides a unique **Micro-Inflation syringe** with a fixed fluid volume for a specific vessel size.	The PercuSurge® GuardWire® II Temporary Occlusion and Aspiration System is comprised of four principal components: the GuardWire® II Temporary Occlusion Catheter, the MicroSeal™ Adapter the Export® Aspiration Catheter and the EZ Flator Inflation/Deflation device. *The system description is identical except for the substitution of the single EZ Flator Inflation/Deflation Device used for inflation, deflation and catheter preparation.* This one syringe accommodates the original vessel diameter of 3.0mm to 6.0mm with a fluid volume for the specified vessel size. Controlled volume delivery is identical. It has an integrated deflation syringe used for catheter preparation and balloon deflation, and also used as a reservoir for diluted contrast solution.

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Indications for Use:	The TOB System is indicated for use in the peripheral vasculature to facilitate the localized infusion of therapeutic or diagnostic fluids with or without vessel occlusion.	The PercuSurge GuardWire Plus Temporary Occlusion & Aspiration System is indicated for use in the coronary saphenous vein bypass grafts to: • Contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures. • To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.
Biocompatibility Data:	Cytotoxicity Study: ISO Elution Sensitization Study in Guinea Pigs Acute Intracutaneous Reactivity Study in the Rabbit Acute Toxicity Study in the Mouse Hemolysis Study In-Vivo In-Vivo Thromboresistence Study Rabbit Pyrogen Study	Identical
Sterilization Method Validation Protocol	EtO	EtO
Labeling	Instructions For Use, Pouch Labels, Box Labels (see K972777 submitted July 23, 1997, section VI).	System Instructions For Use, Pouch labels, Box Labels (see examples starting on page 4).

Non Clinical Performance Data Summary

Vessel Occlusion

The objective of this study was to demonstrate that the individual PercuSurge system components listed below perform as a *system* and provide temporary occlusion under the previously stated pressure and flow rate conditions in vessel sizes of 4mm and 5mm. In summary, in all cases the GuardWire elastomeric occlusion balloon consistently occluded both 4 and 5mm vessels which were subjected to pressures recorded from 1.0-3.5 psi, and flow rates recorded from 70-85 cc/min. These conditions were selected because they

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represent the range of blood pressures and flow rates that the system is expected to see in clinical use.

Fluid Evacuation

The objective of this study was to demonstrate that using the individual system components listed below, different types of fluids (i.e. saline, water, 40% glycerol / 60% saline) can be evacuated from a vessel at a minimum rate of 0.5ml/sec. In all cases, the GuardWire System Accessory Catheter and ancillary components were capable of evacuating all three types of fluids. In addition the flow rates obtained exceeded the minimum specification of 0.5ml/sec as established in conjunction with the PercuSurge Medical Advisory Board.

Particle Evacuation

The objective of this study was to demonstrate that the individual PercuSurge System components identified below could be used to evacuate particulates that were representative of the type of debris that may be found in blood following interventional procedures. It is concluded from this testing that the GuardWire System Accessory (Export) Catheter and ancillary components are capable of evacuating at least 90% of particles. This meets the evacuation capability requirement established by PercuSurge and in conjunction with the PercuSurge Medical Advisory Board. All components performed according to their individual specifications.

Infusion Flow Rate

The purpose of this qualification is to demonstrate that the 8F *Export*® Aspiration Catheter meets pre-determined specifications and test acceptance criteria after EtO sterilization. These fluids were selected to characterize the Accessory Catheter infusion capabilities because they are fluids commonly infused in interventional applications. The testing conducted on the Export Aspiration Catheter demonstrates with the required statistical confidence that the current design meets all of the product specification requirements.

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Additional Laboratory Studies

The evaluation of 40 aspirates from different phases of the therapeutic procedures provided an opportunity to further corroborate the animal studies by determining the nature of the material and its cellular component.

The conclusion from this analysis is that the occlusion balloon and blood removal by aspiration did not affect the vessel wall in the study cohort.

Animal Studies

The PercuSurge GuardWire System has been studied in 8 separate animal safety and effectiveness studies and in accordance with the Instructions For Use. These pilot studies confirmed the feasibility of this technology.

The GuardWire System was compatible with the interventional devices with which it was tested and it successfully occluded the target vessel. It was capable of delivering fluid and evacuating blood. Flow was restored easily after the conclusion of each study. Further, the histopathology results showed that the use of the device had no significant adverse effects on the vessel in which it was used.

Four additional animal comparative studies were performed to demonstrate the improvements and ease of use in the design modifications on the GuardWire system (GuardWire Plus design). These studies were primarily oriented towards performance evaluation and demonstrated that the modified design was superior based on physician input.

Additional Studies

The first test entitled Particles in Motion Distal to the Therapy Balloon, was completed on 4/12/98 and addresses the question of whether particles would have a tendency to aggregate along the proximal side of the distal occlusion balloon prior to aspiration and after therapy. The analyses and studies indicate that the use of a distal or proximal occlusive device does not have an effect of particle movement from therapy dilation. The particles from therapy dilation would not aggregate at the balloon proximal surface during deflation or removal of the therapy balloon. The presence of a distal occlusion balloon would not be expected to enhance particle adherence to a stent due to minor oscillation of the particles from heart rhythm.

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Clinical Performance Data (SAFER Study Data Results Summary)

Table 3. Major Adverse Events – In- and Out-of-Hospital (to 30 days)
All Patients Treated (N=801 Patients, 875 Lesions) Data listed as per patient

	GuardWire™ (N=406 Patients, N=442 Lesions)		No GuardWire™ (N=395 Patients, N=433 Lesions)		All Randomized (N=801 Patients, N=875 Lesions)	
Combined In- and Out-of-Hospital Complications (to 30 days)	Number	%	Number	%	Number	%
MACE (Death, MI, Emergent CABG, TVR)	39	9.6%	65	16.5%	104	13.0%
Death	4	1.0%	9	2.3%	13	1.6%
Myocardial Infarction (Q wave or non-Q wave)	35	8.6%	58	14.7%	93	11.6%
Q Wave MI	5	1.2%	5	1.3%	10	1.2%
Non-Q Wave MI	30	7.4%	54	13.7%	84	10.5%
Emergent CABG	0	0.0%	2	0.5%	2	0.2%
Target Lesion Revascularization	4	1.0%	8	2.0%	12	1.5%
TL-CABG	0	0.0%	1	0.3%	1	0.1%
TL-PTCA	4	1.0%	7	1.8%	11	1.4%
Target Vessel Revascularization not involving the Target Lesion	5	1.2%	2	0.5%	7	0.9%
TV/non-TL-CABG	0	0.0%	0	0.0%	0	0.0%
TV/non-TL-PTCA	5	1.2%	2	0.5%	7	0.9%
Transfusion	21	5.2%	22	5.6%	43	5.4%
Vascular Surgical Repair	4	1.0%	13	3.3%	17	2.1%
Cerebrovascular Accident (CVA)	3	0.7%	0	0.0%	3	0.4%
Perforation	1	0.2%	6	1.5%	7	0.9%
Subacute Closure	5	1.2%	6	1.5%	11	1.4%
Hemorrhagic/Vascular	16	3.9%	22	5.6%	38	4.7%

Conclusions

The results as delineated above, support the benefits of use of the GuardWire system for the target population, outweigh the risk of illness or injury when used as indicated in accordance with the Instruction For Use.

Prior Clinical Study Results

Prior to the initiation of the SAFER randomized study, PercuSurge sponsored and conducted two consecutive feasibility studies to establish the feasibility and initial clinical performance of the PercuSurge GuardWire System. The first feasibility study was conducted as a registry in a single center under the direction of John Webb MD, FRCPC, FACC, Director of Interventional Cardiology, St. Paul's Hospital, Vancouver, B.C., Canada. The second feasibility study was conducted as a multi-center prospective registry under the direction of

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Professor Eberhard Grube MD, Director of Cardiology, Siegburg Heart Center, Siegburg, Germany.

Summaries of both feasibility studies follow below.

1. Feasibility 1 – Single Center Experience

To establish the safety and clinical performance of the PercuSurge GuardWire System, PercuSurge in cooperation with John Webb MD, FRCPC, FACC, Director of Interventional Cardiology, St. Paul's Hospital, Vancouver, B.C., Canada, conducted a study where 30 lesions, (20 patients, 24 procedures) were treated with PTCA and/or stented in conjunction with the PercuSurge GuardWire (then known as the TOBC System). Pursuant to Section 15.2 of the Canadian Medical Devices Regulation, PercuSurge submitted the clinical protocol to the Canadian Devices Bureau, Ottawa, Ontario on March 28, 1997. The clinical study was approved on May 2, 1997 (File Number IU-CV00797). The study was also approved by the University of British Columbia Office of Research Services Administration, Clinical Research Ethics Board on July 22, 1997 (File Number C97-0235) and the St. Paul's Hospital Ethics Committee for human experimentation (File Number P97-0065).

No. of Patients Treated	20
No. of Procedures Performed	24
No. of Lesions Treated	30
Age of SVG in Years	8.7 ± 5.0
Duration	7/30/97 - 1/9/98

Table 4: Study Baseline Information

	Vessel Perforation	Non-Q Wave MI	Q-Wave MI	Emergency CABG	Death	Total
Count of Patient	0	1*	0	0	0	1
Percentage	0%	4%	0%	0%	0%	4%
Relationship to Device	N/A	0	N/A	N/A	N/A	0

Table 5: Acute Complications: Procedure N=24

* Non-Q Wave MI: determined by >3x enzyme

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Conclusions

The data demonstrate that the PercuSurge GuardWire System is safe. It is compatible with routine angioplasty and stent deployment. It can be used in conjunction with interventional devices without affecting the safety of the patient, outcome of the intervention or integrity of the balloon.

2. Feasibility 2 – Multi-Center Experience

A multi-center prospective non-randomized consecutive pilot trial, entitled the SAFE Study, "Saphenous Vein Graft Angioplasty Free of Emboli," was conducted as a multi-center prospective registry under the direction of Professor Eberhard Grube MD, Director of Cardiology, Siegburg Heart Center, Siegburg, Germany The purpose of the SAFE study was to determine the safety and efficacy of treatment with the PercuSurge GuardWire system during stenting in saphenous vein bypass grafts . Ten sites were utilized in Canada, Germany, and Italy. In addition, independent data analysis for this study was conducted by CDAC-Cardiovascular Data Analysis Center, Beth Israel Deaconess Medical and Harvard Medical Centers and independent investigational site monitoring was conducted by MedPass International of Paris, France.

Table 6. Principal Effectiveness and Safety Results
All Patients Treated (N=103 Patients, 105 Lesions)
(on following page)

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Efficacy Measures	All Patients (N=103 Patients, N=105 Lesions)
Lesion Success	99.0% (104 / 105)
Procedure Success	95.1% (98 / 103)
Device Success	85.4% (88 / 103)
Post-Procedure In-Stent MLD (mm)	3.10±0.54 (91) (1.88,4.52)
Post-Procedure In-Stent % DS	6.6%±14.0%(91) (-41.8%,40.0%)
TLR-Free at 30 Days*	99.0%
TVR-Free at 30 Days*	99.0%
TVF-Free at 30 Days*	94.1%
MACE-Free at 30 Days*	94.1%
Safety Measures and Other Clinical Events	
In-Hospital MACE	4.9% (5 / 103)
Out-of-Hospital MACE	1.0% (1 / 103)
Stent Thrombosis to 30 days	1.0% (1 / 103)
Bleeding Complications to 30 days	1.9% (2 / 103)
Vascular Complications to 30 days	3.9% (4 / 103)
CVA to 30 days	0.0% (0 / 103)

Numbers are % (counts/sample size) and Mean ± SD.
*Survival estimates by Kaplan-Meier method.
Lesion Success = Attainment of <50% residual stenosis using any percutaneous method, e.g., the assigned treatment followed by another device (such as an additional stent). If no in-stent measurements were available, in-lesion measurements were used, and if no QCA was available, visual estimates were used.

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Procedure Success = Attainment of <50% final diameter stenosis using any percutaneous method without the occurrence of in-hospital death, MI, or target vessel revascularization. If no in-stent measurements were available, in-lesion measurements were used, and if no QCA was available, visual estimates were used.
Device Success = Deployment, occlusion of flow by crossing the lesion, and inflation and aspiration per Instructions For Use.
TLR-Free = No clinically-driven target lesion revascularization.
TVR-Free = No clinically-driven repeat percutaneous intervention of the target vessel or bypass surgery of the target vessel.
TVF-Free = No target vessel revascularization, MI, or death that could not be clearly attributed to a vessel other than the target vessel.
MACE-Free = No death, Q wave or non-Q wave MI, emergent bypass surgery, or target vessel revascularization.
In-Hospital MACE = Death, Q wave or non-Q wave MI, emergent bypass surgery, or target vessel revascularization prior to hospital discharge as determined by the independent Clinical Events Committee.
Out-of-Hospital MACE = Death, Q wave or non-Q wave MI, emergent bypass surgery, or target vessel revascularization after hospital discharge, as determined by the independent Clinical Events Committee.
Stent Thrombosis = Angiographic thrombus or subacute closure within the stented vessel, or any death not attributed to a non-cardiac cause in the absence of documented angiographic stent patency within the first 30 days.
Bleeding Complications = Transfusions of blood products due to blood loss from the index percutaneous revascularization procedure.
Vascular Complications = Hematoma at access site >4 cm, false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, procedure related transfusion or vascular surgical repair.
CVA = Acute neurological deficits recorded by the clinical sites that persisted >24 hours.

Conclusions: The PercuSurge® GuardWire Plus™ System is compatible with routine angioplasty procedures, is capable on containing and retrieving atherosclerotic and thrombotic debris, and may aid in the prevention of distal embolization and "no-reflow" in diseased saphenous vein grafts.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2001

Ms. Debora D. Hinman
Vice President, Regulatory Affairs and Quality Assurance
PercuSurge, Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

Re: K003992
The PercuSurge GuardWire Plus Temporary Occulusion & Aspiration System
Regulation Number: 870.1250
Regulatory Class: II (two)
Product Code: 74 NFA
Dated: March 29, 2001
Received: March 30, 2001

Dear Ms. Hinman:

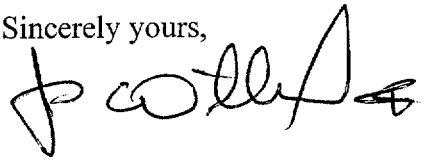
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K003992

Device Name: PercuSurge GuardWire Temporary Occlusion and Aspiration System

Indications for Use:

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- To subselectively infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.
- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003992