

K972290

SEP 17 1997

**APPENDIX VI**  
**SUMMARY OF SAFETY AND EFFECTIVENESS**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990.

1. **Trade Name:** ACS HI-TORQUE RULER™ Guide Wire

**Common Name:** Guide Wire

2. **Device Classification:** Vascular guide wire

3. **Performance Standards:**

Performance standards have not been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for vascular guide wires.

4. **Device Description:**

ACS HI-TORQUE RULER™ Guide Wire

The ACS HI-TORQUE RULER™ Guide Wire is a steerable guide wire intended to facilitate placement of balloon dilatation catheters during Percutaneous Transluminal Coronary Angioplasty (PTCA) and Percutaneous Transluminal Angioplasty (PTA), and other diagnostic and therapeutic intravascular procedures. It is not intended for use in the cerebral vasculature or for use with atherectomy devices.

The proximal and distal portions of the guide wire are constructed from a core assembly. A series of tapers, which reduce the diameter of the core wire distally, yields the desired tip flexibility. The distal 30 centimeters proximal to the tip of the ACS HI-TORQUE RULER™ Guide Wire are coated with Microglide® while the remaining portion is coated with polytetrafluoroethylene (PTFE). Both coatings are intended to reduce friction for improved movement of the wire within the catheter. The platinum alloy coils provide the physicians with a radiopaque tip.

5. **Summary of Substantial Equivalence:**

A comparison of the ACS HI-TORQUE RULER™ Guide Wire to the predicate ACS Hi-Torque Extra S'Port™ (K942066 and K950156) indicates that the new guide wire is substantially equivalent to the predicate guide wire with regard to the intended use, materials and design.

The ACS HI-TORQUE RULER™ Guide Wire is a steerable guide wire intended to facilitate placement of balloon dilatation catheters during Percutaneous Transluminal Coronary Angioplasty (PTCA) and Percutaneous Transluminal Angioplasty (PTA), and other diagnostic and therapeutic intravascular procedures. It is not intended for use in the cerebral vasculature or for use with atherectomy devices. The intended use of the ACS HI-TORQUE RULER™ Guide Wire is equivalent to the predicate guide wire noted above.

The materials used in the manufacture of the ACS HI-TORQUE RULER™ Guide Wire are similar to those in the predicate ACS Hi-Torque Extra S'Port™

The design of the new ACS HI-TORQUE RULER™ Guide Wire is constructed from a stainless steel core wire which extends into the distal-most solder of the guide wire. This feature is identical to that of the .014" ACS Hi-Torque Extra S'Port™ Guide Wire. Like the predicate ACS Hi-Torque Extra S'Port™ guide wire, the new guide wire design includes a series of tapers and flats which reduce the diameter of the core wire distally, yielding the desired tip flexibility. Like the predicate ACS Hi-Torque Extra S'Port™ guide wire the intermediate coils are eliminated in the new design. Unlike the ACS Hi-Torque Extra S'port Guide Wire, the ACS HI-TORQUE RULER™ Guide Wire contains a series of Pt/Ir radiopaque bands attached onto the core wire using laser heat. Also, a polyimide tubing has been added to the intermediate portion of the core wire extending from the proximal end of the tip coil to the distal portion of the proximal taper. Additionally, proximal markers created by stripping and cleaning areas of Teflon are positioned at 90 cm and 100 cm from the distal tip of the guide wire. These proximal markers aid the physician in gauging wire position relative to a brachial or femoral guiding catheter tip when using a "bare wire" technique.

6. **Testing Data:**

Biocompatibility

Materials for the ACS HI-TORQUE RULER™ Guide Wire are identical to those of the predicate ACS Hi-Torque Extra S'port™ Guide Wire, with the exception of the addition of Pt/Ir bands and polyimide tubing. Therefore,

biocompatibility testing was completed on the ACS HI-TORQUE RULER™ Guide Wire. The results of this testing are summarized below:

<b>Test Completed</b>	<b>Results</b>
<b>Cytotoxicity Test</b>	Non-cytotoxic
<b>Hemolysis</b>	Non-hemolytic
<b>Systemic Injection Test</b>	Pass
<b>Intracutaneous Test</b>	Pass
<b>Intramuscular Implant Test</b>	Pass
<b>Sensitization Test</b>	Pass
<b>LAL Pyrogen Test</b>	Non-pyrogenic

### Bench Testing

The strength of the polyimide adhesion of the ACS HI-TORQUE RULER™ Guide Wire was determined by a pull test. These tests demonstrated that the strength of the polyimide adhesive of the ACS HI-TORQUE RULER™ Guide Wire is acceptable.

The strength of the laser weld of the platinum bands on the ACS HI-TORQUE RULER™ Guide Wire was determined by a pull test. These tests demonstrated that the strength of the laser weld on the platinum bands on the ACS HI-TORQUE RULER™ Guide Wire is acceptable.

The tensile strengths of the guide wire distal tip were determined by a pull test. These tests demonstrated that the ACS HI-TORQUE RULER™ Guide Wire has adequate tensile strength.

The torsional strength of the distal tip was determined by a turns-to-failure test. This test showed that the ACS HI-TORQUE RULER™ Guide Wire has adequate torsional tip strength.

The tip flexibility testing demonstrated that tip flexibility of the ACS HI-TORQUE RULER™ Guide Wire is equivalent to that of the predicate and is acceptable.

The correlation between rotation of the proximal end and the corresponding rotation of the distal end of the guide wire was determined by the rotational accuracy test. This test showed that the ACS HI-TORQUE RULER™ Guide Wire has 1:1 torque response.

### Animal Testing

Initial animal testing identified an issue related to guide wire movement of the RULER™ wire within interventional devices. This problem was determined to be a result of inadequate Microglide® application to the polyimide sheath on the distal portion of the wire. An improved Microglide® application process was implemented and two subsequent animal studies confirmed that the RULER™ guide wire has acceptable clinical performance in compatible balloon dilatation catheters and stent delivery devices. However, using the RULER™ wire with atherectomy devices is not indicated since the polyimide sheath may become caught and/or impede the cutter of the device. Therefore, the ACS HI-TORQUE RULER™ Guide Wire is contraindicated for use with atherectomy devices.

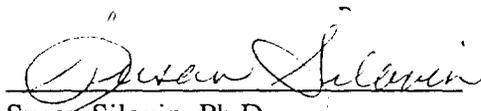
7. **Sterilization:**

The ACS HI-TORQUE RULER™ Guide Wire is sterilized by the same methods and following the same parameters as those used for the predicate ACS Hi-Torque Extra S'Port™ Guide Wire (K942066, 4/28/94 and K950156, 1/16/95).

8. **Conclusion:**

The ACS HI-TORQUE RULER™ Guide Wire is substantially equivalent to the predicate ACS Hi-Torque Extra S'Port™ Guide Wire (K942066, 4/28/94 and K950156, 1/16/95).

Signed:



Susan Silavin, Ph.D.

Regulatory Affairs Coordinator



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 17 1997

Susan Silavin, Ph.D.  
Guidant Corporation  
c/o Advanced Cardiovascular Systems  
3200 Lakeside Drive  
P.O. Box 58167  
Santa Clara, California 95052-8167

Re: K972290  
ACS HI-TORQUE RULER™ Guide Wire  
Regulatory Class: II (two)  
Product Code: 74 DQX  
Dated: June 18, 1997  
Received: June 19, 1997

Dear Dr. Silavin:

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 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.

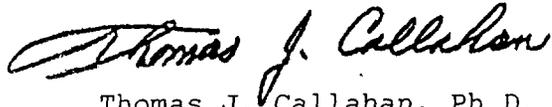
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, 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 pre-market 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) 594-4639. 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" (21 CFR 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/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K972290

Device Name: ACS HI-TORQUE RULER™ Guide Wire

Indications for Use:

The ACS HI-TORQUE RULER™ Guide Wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA), or percutaneous transluminal angioplasty (PTA). The wire is also intended to facilitate the placement of equipment, such as compatible stent devices, during other diagnostic and therapeutic intravascular procedures. It should not be used with atherectomy devices. It is not intended for use in the cerebral vasculature.

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IF NEEDED)

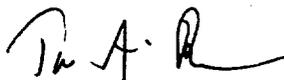
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter \_\_\_\_\_

(Optional Format 1-1-96)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K 972290