

4/29/99

K991152 31

## ATTACHMENT 4

### 510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

1. Submitter's Name: Guidant Corporation  
Advanced Cardiovascular Systems, Inc.
2. Submitter's Address: 3200 Lakeside Drive  
Santa Clara, CA 95054
3. Telephone: 408-235-3995
4. Fax: 408-235-3743
5. Contact Person: Margaret Anderson
6. Date Prepared: April 5, 1999
7. Device Trade Name: HI-TORQUE BALANCE TREK™ Guide Wires with  
HYDROCOAT™ Hydrophilic Coating
8. Device Common Name: Guide Wire
9. Device Classification Name: Catheter Guide Wire  
(74DQX)
10. Predicate Device: ACS HI-TORQUE BALANCE HEAVYWEIGHT™ Guide  
Wire with HYDROCOAT™ Hydrophilic Coating (K982083)

#### 11. Device Description:

The HI-TORQUE BALANCE TREK™ Guide Wire with HYDROCOAT™ Hydrophilic Coating is a steerable guide wire with a maximum diameter of 0.014" and available in: 175 cm and 190 cm extendable lengths and a 300 cm exchange length. The proximal end of the 175 cm and 190 cm models are tapered to fit into the hypotube portion of the ACS DOC® Guide Wire Extension. The distal end of the guide wire has a radiopaque tip that are available either as a straight or as a preshaped J. The hydrophilic coating is applied to the distal portion of the wire guide wire. The proximal section of the guide wire is coated with polytetrafluoroethylene.

#### 12. Intended Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The wire is also intended to facilitate the placement of equipment such as atherectomy and compatible stent devices during other diagnostic and therapeutic procedures.

#### 13. Technological Characteristics:

Comparisons of the new and predicate devices show that technological characteristics such as materials, biocompatibility, performance properties, sterilization, and packaging are identical or substantially equivalent to the currently marketed predicate device. The design modifications of the new guide wire compared to that of the predicate wire are the modified core and tip coils.

#### 14. Performance Data:

*In vitro* bench testing and *in vivo* performance evaluations were performed to demonstrate that the HI-TORQUE BALANCE TREK™ Guide Wire with HYDROCOAT™ Hydrophilic Coating met the acceptance criteria and performed similar to the predicate device. The following functional tests were performed: Distal Tip Pull Test, Distal Tip Turns-to-Failure Test, Rotational Accuracy Test and Tip Flexibility Test.

The results from the tests demonstrated that the new The HI-TORQUE BALANCE TREK™ Guide Wires met the acceptance criteria and performed in a manner equivalent the predicate ACS HI-TORQUE BALANCE HEAVYWEIGHT™ Guide Wire. No new safety or effectiveness issues were raised during the testing program.

## 15. Conclusions

Since the new guide wire has the same intended use, materials, technological characteristics, performance properties, identical sterilization and packaging, and no new safety or effectiveness issues, the HI-TORQUE BALANCE TREK™ Guide Wire with HYDROCOAT™ Hydrophilic Coating may be considered substantially equivalent to the predicate ACS HI-TORQUE BALANCE HEAVYWEIGHT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 29 1999

Ms. Margaret Anderson  
Regulatory Affairs  
Guidant Corporation  
P.O. Box 58167  
Santa Clara, CA 95052

Re: K991152  
Trade Name: HI-TORQUE BALANCE TREK™ Guide Wires with  
HYDROCOAT™ Hydrophilic Coating  
Regulatory Class: II  
Product Code: DQX  
Dated: April 5, 1999  
Received: April 6, 1999

Dear Mr. Anderson:

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,



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

Enclosure

# ATTACHMENT 2

## Indications for Use Statement

510(k) Number  
(if known)

Device Name

HI-TORQUE BALANCE TREK™ Guide Wires with HYDROCOAT™ Hydrophilic Coating

Indications for Use

The intended use for the HI-TORQUE BALANCE TREK™ Guide Wires with HYDROCOAT™ Hydrophilic Coating is:

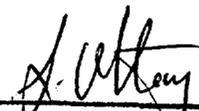
To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The wire is also intended to facilitate the placement of equipment such as atherectomy and compatible stent devices during other diagnostic and therapeutic procedures.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

OR Over-The-Counter

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number           K991152