510(k) SUMMARY

JUL 3 1 2006

Submitter	Guidant Corporation, Cardiac Surgery
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Contact Person	Christina L. Rowe
Date Prepared	July 11, 2006
Device Trade Name	Guidant FLEXView™ System
Device Common Name	Endoscope, accessories
Device Classification Name	Endoscope, accessories
Device Classification	Class II
Summary of substantial equivalence	The design, materials, method of delivery, features, and intended use of the Guidant FLEXView™ System are substantially equivalent to the predicate devices: VasoView® Endoscopic Vessel Harvesting System (VV4), (K030512, cleared on May 10, 2003) and VasoView® 6 Harvesting Cannula (K041981, cleared on August 20, 2004).
Device description	The FLEXView™ System includes the following components: the Cannula Assembly (with fixed, integrated visualization lens), the Routing Snare, and the Retrieval Tool. The Cannula Assembly mates a plastic lens to the tip of a Guidant 7mm Extended Length Endoscope, to enable visualization of anatomy in dry or wet environments (including in contact with tissue). This Cannula is delivered to the surgical site by way of a surgical port. The Cannula Assembly has a total of three lumens. The largest of these receives the 7mm Extended Length Endoscope. The other two lumens are intended to receive the Routing Snare, which consists of a sheathed wire with loops at either end, and then subsequently the Retrieval Tool, which is a sheathed stainless steel shaft with an exposed stainless steel ball at its tip. After delivering the Routing Snare via the service port to the position of interest within the thoracic space, the Retrieval Tool enables capture of the Snare by providing a retaining feature for engagement. The Routing Snare can then be used to route and place another surgical instrument such as the Guidant Microwave Ablation Probe. The FLEXView™ System is a single use device, supplied sterile.

510(k) SUMMARY (continued)

Indications for Use	The FLEXView™ System is indicated for use in minimally invasive surgery allowing access for delivery and placement of surgical instruments (e.g., Guidant Microwave Ablation Probe). It is indicated for patients requiring blunt dissection of tissue including structures in the thoracic space.
Technological characteristics	The Guidant FLEXView™ System incorporates similar fundamental scientific technology as its predicate devices.
Performance data	The results of verification testing demonstrate that the FLEXView™ System meets the established acceptance criteria and performs in a manner equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 1 2006

Boston Scientific
% Underwriters Laboratories, Inc.
Mr. Morten Simon Christensen
455 E. Trimble Road
San Jose, California 95131-1230

Re: K062050
Trade/Device Name: Guidant FLEXView™ System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: July 18, 2006
Received: July 20, 2006

Dear Mr. Christensen:

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,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062050

INDICATIONS FOR USE STATEMENT

510(k) number (if known)	The 510(k) number has not been issued yet.
Device name	Guidant FLEXView™ System
Indications for Use	The Guidant FLEXView™ System is indicated for use in minimally invasive surgery allowing access for delivery and placement of surgical instruments (e.g., Guidant Microwave Ablation Probe). It is indicated for patients requiring blunt dissection of tissue including structures in the thoracic space.

Prescription Use ___X___ (21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K062050