

**AUG 15 2006**

**SureSave<sup>™</sup>**  
**Self-Expandable Biliary Nitinol Stent and Precision<sup>™</sup> Stent Delivery Catheter**  
**510(k) Summary**

**Submitter:** IDev Technologies, Inc.  
1120 NASA Road One, Suite 600  
Houston, Texas 77058

**Contact Person:** Timothy R. Placek  
Vice President, Regulatory Affairs, Clinical Affairs and Quality  
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**Date Prepared:** March 1, 2006

**Trade Name:** SureSave<sup>™</sup> Self-Expandable Biliary Nitinol Stent and Precision<sup>™</sup> Stent  
Delivery Catheter

**Product Code:** FGE

**Predicate Device:** Protege<sup>®</sup> GPST<sup>™</sup> Self-Expanding Nitinol Stent – Biliary (K051379)  
SMART<sup>™</sup> Control<sup>™</sup> Nitinol Stent Transhepatic - Biliary (K032457)

**Device Description:**

The SureSave<sup>™</sup> Self-Expandable Biliary Nitinol Stent and Precision<sup>™</sup> Stent Delivery Catheter is comprised of two components; the implantable SureSave<sup>™</sup> metallic stent and the Precision<sup>™</sup> delivery system. The stent, provided pre-mounted on the delivery system, is a woven wire is constructed from a biomedical superalloy wire, braided in a tubular mesh configuration. The design configuration results in a stent that is flexible, compliant, self-expanding and can withstand strong radial force. The delivery system consists of an inner and outer catheter. The exterior catheter serves to constrain the stent until retracted during delivery. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. The inner catheter contains a central lumen which will accommodate a 0.018" guidewire.

**Intended Use:**

The SureSave<sup>™</sup> Self-Expandable Biliary Nitinol Stent and Precision<sup>™</sup> Stent Delivery Catheter is indicated for palliative treatment of biliary strictures produced by malignant neoplasms.

**Technological Characteristics Compared to Predicate**

The SureSave<sup>™</sup> Self-Expandable Biliary Nitinol Stent and Precision<sup>™</sup> Stent Delivery Catheter is substantially equivalent to the predicate devices. The equivalence was confirmed through preclinical testing.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Timothy R. Placek  
VP of Regulatory Affairs, Clinical Affairs  
and Quality Systems  
Official Correspondent  
IDev<sup>®</sup> Technologies, Inc.  
1120 NASA Road One, Suite 600  
HOUSTON TX 77058

Re: K060557

Trade/Device Name: SureSave<sup>™</sup> Self-Expandable Biliary Nitinol Stent and Precision<sup>™</sup>  
Stent Delivery Catheter

Regulation Number: 21 CFR §876.5010

Regulation Name: Biliary catheter and accessories

Regulatory Class: II

Product Code: 78 FGE

Dated: July 7, 2006

Received: July 10, 2006

Dear Mr. Placek:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

If you desire specific information about the application of other labeling requirements to your device (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" (21 CFR 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Donna-Bea Tillman, Ph.D., M.P.A.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K060557

Device Name: SureSave™ Self-Expandable Biliary Nitinol Stent and Precision™ Stent Delivery Catheter

**FDA Indications For Use:** The SureSave™ Self-Expandable Biliary Nitinol Stent and Precision™ Stent Delivery Catheter is intended for use in the palliation of malignant neoplasms in the biliary tree.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

~~AND/OR~~

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*David B. Seymour*

(Division Sign-Off)  
Division of Reproductive, Abdominal, and  
Radiological Devices

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