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510(k) Summary of Safety and Effectiveness

Submitter: IDev® Technologies, Inc.
1120 NASA Parkway, Suite 600
Houston, Texas 77058
FDA Establishment Registration Number: 3005325609

Contact Person: Timothy R. Placek
Vice President, Regulatory Affairs, Clinical Affairs and Quality Systems
(281) 333-1998 (Phone)
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Date Prepared: June 8, 2007

Trade Name: SUPERA™ Interwoven Self-Expanding Nitinol Biliary Stent Delivery Catheter

Common Name: Biliary Stent Delivery Catheter

Product Class/Code: Class II/FGE

Predicate Device: Precision™ Stent Delivery Catheter (K060557)

Device Description:

The SUPERA™ Interwoven Self-Expanding Nitinol Biliary Stent Delivery Catheter was designed and is manufactured by IDev Technologies, Inc. for use with the FDA 510(k) cleared SureSave™ Self-Expandable Biliary Nitinol Stent (K060557), a.k.a. SUPERA™ biliary nitinol stent, in the palliation of malignant strictures (neoplasms) in the biliary tree. It shares the same indication for use and design features as the Precision™ Stent Delivery Catheter (K060557) with the exception of modifications that do not significantly affect the function and/or safety of the device.

Please refer to Figure 1. The SUPERA™ Interwoven Self-Expanding Nitinol Biliary Stent Delivery Catheter is a 7 Fr, 0.018" guide wire compatible, multi-lumen sheath based delivery system comprised of an Outer Sheath (1) attached proximally to a Handle (2); a radiopaque Marker Band (3) located on the Outer Sheath that can be visualized under fluoroscopy to assist in system placement/SUPERA™ stent deployment; a Thumb Slide (4) connected internally to a means for advancing the SUPERA™ stent out of the Outer Sheath as the Outer Sheath moves proximally in a de-coupled fashion; a Stopcock (5) for flushing the central lumen of the device

and for contrast injection; a Retention Cable (6) connected to the proximal end of a stent to assist in resheathing/repositioning the stent; a Resheath Collar (7) that can be actuated to allow for resheathing or deployment of a stent; a Torquer (8) connected to the Retention Cable for external visualization of the deployment process; a dedicated Guidewire Lumen (9) for traversing over an 0.018" guidewire with a radiopaque Flexible Tip (10) and Guidewire Luer Fitting (11), used for flushing the Guidewire Lumen, located on the distal and proximal end of the Guidewire Lumen, respectively; a Hemostasis Valve (12) that can be tightened to eliminate relative motion of the Flexible Tip with respect to the Outer Sheath; a Y-Port (13) housing the Retention Cable and serving as a point of reference for deployment; an introducer Valve Defeater (14); a Re-Sheathing Indicator (15); and a Packaging Mandrel (16).

Stent deployment is accomplished by advancing the Thumb Slide distally, while holding the Handle stationary, until the Thumb Slide reaches the Resheath Collar. This distal motion of the Thumb Slide will introduce a small segment of stent into the biliary duct as the Outer Sheath moves proximally in a de-coupled fashion. Following location confirmation, the Thumb Slide is moved back into the proximal position to engage another portion of the stent and then advanced distally, once again, until it reaches the Resheath Collar. Thumb Slide proximal to distal motion will continue until only a small portion of the stent remains within the Outer Sheath, as visualized by the Torquer approaching the Y-Port, at which time an election to deploy or resheath/reposition the stent is made.

If deployment is desired the:

a) Thumb slide is placed in the proximal most position;
b) Resheath Collar is rotated clockwise allowing for the Thumb slide to move into a position distal to the Resheath Collar;
c) Thumb Slide is moved into the distal most position;
d) deployment is confirmed under fluoroscopy; and
e) SUPERA™ Interwoven Self-Expanding Nitinol Biliary Stent Delivery Catheter is removed.

If resheathing/repositioning is desired the:

a) Resheath Collar is rotated clockwise allowing for the Thumb slide to move into a position distal to the Resheath Collar;
b) Thumb Slide is advanced distally without moving it into the proximal most position;
c) Guidewire Luer fitting is moved proximally;
d) Torquer is pulled proximally until the stent is resheathed; and
e) Thumb Slide is moved into the proximal most position.

Intended Use:

The SUPERA™ Interwoven Self-Expanding Nitinol Biliary Stent Delivery Catheter is indicated for use with the FDA 510(k) cleared SureSave™ Self-Expandable Biliary Nitinol Stent

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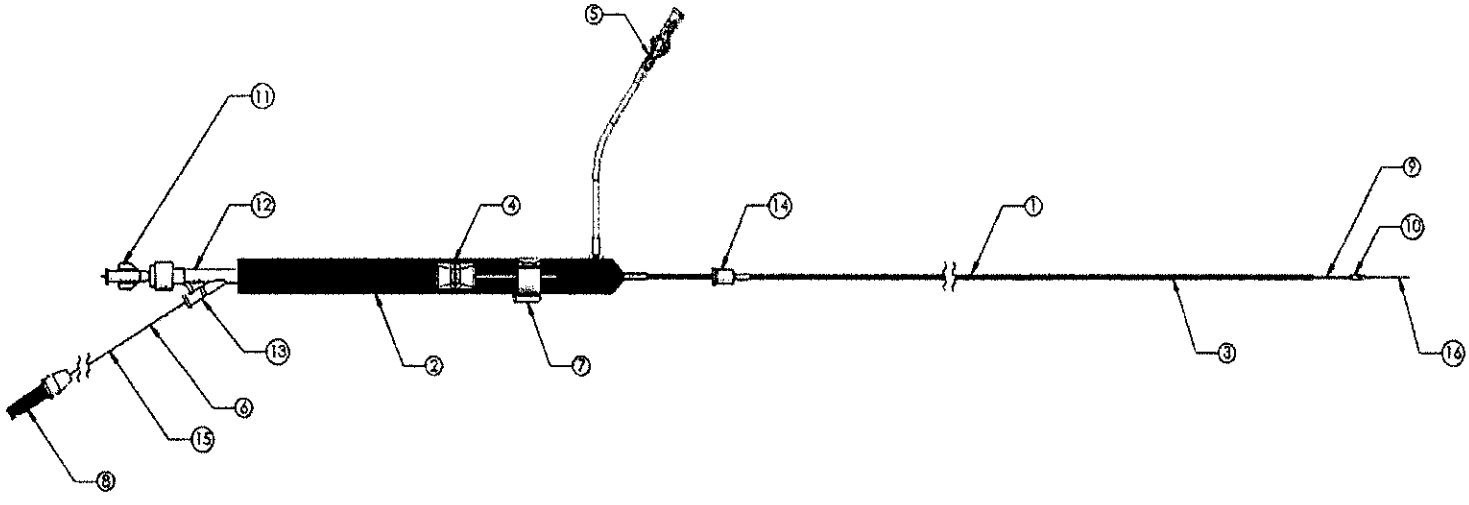
(K060557), a.k.a. SUPERA™ biliary nitinol stent, in palliative treatment of biliary strictures produced by malignant neoplasms.

Technological Characteristics Compared to Predicate

The SUPERA™ Interwoven Self-Expanding Nitinol Biliary Stent Delivery Catheter is substantially equivalent to the predicate device. The equivalence was confirmed through preclinical testing.

Figure 1.



SUPERA™ Interwoven Self-Expanding Nitinol Biliary Stent Delivery Catheter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2008

Mr. Timothy R. Placek
Vice President, Regulatory Affairs,
Clinical Affairs and Quality Systems
IDEV® Technologies, Inc.
1120 NASA Parkway, Suite 600
HOUSTON TX 77058

Re: K071646
Trade/Device Name: SUPERA™ Interwoven Self-Expanding Nitinol Biliary Stent Delivery Catheter
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: December 28, 2007
Received: December 28, 2007

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): K071646

Device Name: SUPERA™ Interwoven Self-Expanding Nitinol Biliary Stent Delivery Catheter

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___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

ision Sign-Off)
sion of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071646