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510(k) Summary

SUPERA VERITAS®
Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System

Submitter: IDEV Technologies, Inc.
253 Medical Center Boulevard
Webster, Texas 77598
281/525-2000

Contact Person: Darlene Garner
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Date Prepared: March 4, 2013

Trade Name: SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System

Common Name: Stent Delivery Catheter

Classification Name: Catheter, Biliary, Diagnostic; Class II

Product Code: FGE

Predicate Devices: SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System (K122546)

Device Description:

The SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System is a 0.014" or 0.018" guidewire compatible, multi-lumen sheath based delivery system and a SUPERA® Biliary Stent. The stent delivery catheter includes a radiopaque Stent Length Marker and Distal Sheath Marker embedded in the Outer Sheath to aid in proper stent positioning; a Thumb Slide connected internally for advancing the Stent out of the Outer Sheath while the Outer Sheath moves proximally in a de-coupled fashion; a Sheath Flush Port for flushing the central lumen of the device; a Deployment Lock that

when actuated enables the final deployment stroke of the stent; a Guidewire Lumen with a radiopaque Catheter Tip located on the distal end of the Catheter Shaft; a Guidewire Flush Port used for flushing the Guidewire Lumen; a Stent Driver (ratchet) which moves the stent distally relative to the Outer Sheath; and the System Lock which eliminates the possibility of premature deployment. The working length of the delivery catheter is 80cm and 120cm.

The SUPERA® Stent is housed within the SUPERA VERITAS® stent delivery catheter and is a closed end interwoven self-expanding Nitinol stent. The SUPERA® stent is composed of 6 interwoven, closed loop Nitinol wires. The wire loops are closed via a proprietary welding process which utilizes small Nitinol tubes that act as a coupler to provide the mechanical means of joining the wire ends. The table below includes the available sizes and model numbers for the SUPERA VERITAS® Stent Delivery System.

Model No.	Stent Diameter	Stent Length	Catheter Length
6Fr System			
S-04-040-80-6F	4mm	40mm	80cm
S-04-060-80-6F	4mm	60mm	80cm
S-04-080-80-6F	4mm	80mm	80cm
S-04-100-80-6F	4mm	100mm	80cm
S-04-120-80-6F	4mm	120mm	80cm
S-05-040-80-6F	5mm	40mm	80cm
S-05-060-80-6F	5mm	60mm	80cm
S-05-080-80-6F	5mm	80mm	80cm
S-05-100-80-6F	5mm	100mm	80cm
S-05-120-80-6F	5mm	120mm	80cm
S-06-040-80-6F	6mm	40mm	80cm
S-06-060-80-6F	6mm	60mm	80cm
S-06-080-80-6F	6mm	80mm	80cm
S-06-100-80-6F	6mm	100mm	80cm
S-06-120-80-6F	6mm	120mm	80cm
S-07-040-80-6F	7mm	40mm	80cm
S-07-060-80-6F	7mm	60mm	80cm
S-07-080-80-6F	7mm	80mm	80cm
S-07-100-80-6F	7mm	100mm	80cm
S-04-040-120-6F	4mm	40mm	120cm
S-04-060-120-6F	4mm	60mm	120cm
S-04-080-120-6F	4mm	80mm	120cm
S-04-100-120-6F	4mm	100mm	120cm
S-04-120-120-6F	4mm	120mm	120cm
S-05-040-120-6F	5mm	40mm	120cm
S-05-060-120-6F	5mm	60mm	120cm
S-05-080-120-6F	5mm	80mm	120cm
S-05-100-120-6F	5mm	100mm	120cm
S-05-120-120-6F	5mm	120mm	120cm
S-06-040-120-6F	6mm	40mm	120cm
S-06-060-120-6F	6mm	60mm	120cm
S-06-080-120-6F	6mm	80mm	120cm
S-06-100-120-6F	6mm	100mm	120cm
S-06-120-120-6F	6mm	120mm	120cm
S-07-040-120-6F	7mm	40mm	120cm
S-07-060-120-6F	7mm	60mm	120cm
S-07-080-120-6F	7mm	80mm	120cm

Model No.	Stent Diameter	Stent Length	Catheter Length
S-07-100-120-6F	7mm	100mm	120cm
7Fr System			
S-04-040-120-G3	4mm	40mm	120cm
S-04-060-120-G3	4mm	60mm	120cm
S-04-080-120-G3	4mm	80mm	120cm
S-04-100-120-G3	4mm	100mm	120cm
S-04-120-120-G3	4mm	120mm	120cm
S-05-040-120-G3	5mm	40mm	120cm
S-05-060-120-G3	5mm	60mm	120cm
S-05-080-120-G3	5mm	80mm	120cm
S-05-100-120-G3	5mm	100mm	120cm
S-05-120-120-G3	5mm	120mm	120cm
S-06-040-120-G3	6mm	40mm	120cm
S-06-060-120-G3	6mm	60mm	120cm
S-06-080-120-G3	6mm	80mm	120cm
S-06-100-120-G3	6mm	100mm	120cm
S-06-120-120-G3	6mm	120mm	120cm
S-06-150-120-G3	6mm	150mm	120cm
S-07-040-120-G3	7mm	40mm	120cm
S-07-060-120-G3	7mm	60mm	120cm
S-07-080-120-G3	7mm	80mm	120cm
S-07-100-120-G3	7mm	100mm	120cm
S-08-040-120-G3	8mm	40mm	120cm
S-08-060-120-G3	8mm	60mm	120cm
S-08-080-120-G3	8mm	80mm	120cm
S-08-100-120-G3	8mm	100mm	120cm

The SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System is a sterile (via Ethylene Oxide sterilization) device and is intended for single use only.

Intended Use:

The SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System is indicated for palliative treatment of biliary strictures produced by malignant neoplasms.

Comparison to Predicate Devices:

The SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System is substantially equivalent to the predicate device, IDEV's SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System (K122546).

A review of the product specifications concluded that there are no differences in design, materials, performance, safety and product effectiveness. Substantial Equivalence to the predicate devices has been demonstrated via bench performance testing.

Testing:

Engineering studies were performed per the FDA's "Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents; ISO 10993 - International

Standard for Biological Evaluation of Medical Devices". Additionally, testing was conducted per ASTM F2516-07e2; ASTM E739-91; ASTM A967-05; ASTM F2129-08; ASTM F2063-05; ASTM E1447-09; ASTM E1409-08; Clinical data was not required in order to demonstrate safety and efficacy for the device modifications described in this 510(k).

Testing
Engineering Study, SUPERA Stent In-house Passivation Process
In-House Passivation Process Validation (IQ and OQ)
Engineering Study, Nickel Ion Release Testing, Vendor Passivated Stent
Nickel Ion Release Testing, In House Passivation
Material Characterization SUPERA Stent Chemical Analysis - In-House Passivation
Raw Material Mechanical Characterization, Nitinol Wire Tension and Rotating Beam Fatigue
Material Characterization SUPERA Stent Chemical Analysis
Raw Material Mechanical Properties Characterization, Nitinol Wire Tensile and Rotating Beam Fatigue Test – In-House Passivation

Testing of the In-house passivated stent verified that the SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System is substantially equivalent to its predicate device. No additional safety risks were observed during testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2013

IDEV Technologies, Inc.
% Ms. Darlene Garner
Regulatory Affairs Director
253 Medical Center Blvd.
WEBSTER TX 77598

Re: K130591
Trade/Device Name: SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: March 5, 2013
Received: March 7, 2013

Dear Ms. Garner:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christy L. Foreman -S

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130591

Device Name: SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System

Indications for Use:

The SUPERA VERITAS® Interwoven Self-Expanding Nitinol Stent Transhepatic Biliary System is indicated for palliative treatment of biliary strictures produced by malignant neoplasms.

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)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130591