K082093

CONFIDENTIAL



**510(k)**
**Summary of Safety and Effectiveness**

JUL 29 2009

**Submitter:** SquareOne, Inc.
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Mountain View, CA 94043
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**Contact:** Eric Ankerud; EVP, Regulatory & Quality

**Date Prepared:** July 22, 2008

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**Trade Name:** BullsEye Biliary Stent System

**Common Name:** Biliary stent

**Classification Name:** Biliary catheter

**Device Classification:** Class II, per 21 CFR 876.5010

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**Summary of Substantial Equivalence:**

A variety of tests, assessments, and comparisons demonstrate that the BullEye Biliary Stent System is substantially equivalent to the Cordis PALMAZ GENESIS Transhepatic Biliary Stent and Delivery System (K010411) and the Bard LUMINEXX 3 Biliary Stent and Delivery System (K033497) in terms of composition, design, intended use, and performance attributes.

**Device Description:**

The BullsEye Biliary Stent System is a 316L stainless steel, balloon-expandable stent design with a 6.2mm diameter and 15mm length (unexpanded). The stent is comprised of a distal cylindrical segment, which provides permanent structural support and subsequently restores and maintains bile flow by scaffolding the duct wall, and a 3.7mm proximal conformable flare segment, which helps to prevent post deployment stent migration and dislocation. The stent is pre-mounted on a dual-balloon, monorail, delivery device with 80cm working length and a crossing profile compatible with guide catheters/introducer sheaths with a minimum inner diameter of 0.081". The system is also compatible with standard 0.014" guidewires. Two radiopaque marker bands aid in positioning of the stent during the delivery procedure.

**Intended Use:**

The BullsEye Biliary Stent System is intended for use in the palliation of malignant neoplasms in the biliary tree.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 2009

Eric P. Ankerud, J.D.
Executive Vice President, Regulatory and Quality
SquareOne, Inc.
510 Clyde Avenue
MOUNTAIN VIEW CA 94043

Re: K082093
Device Name: BullsEye Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: November 21, 2008
Received: November 24, 2008

Dear Mr. Ankerud:

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 (301) 796-5484. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): K082093

Device Name: BullsEye Biliary Stent System

Indications For Use: BullsEye Biliary Stent System is indicated 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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082093