

Section III - 510(k) Summary of Safety and Effectiveness

K 080612

Submitter:

Sybron Dental Specialties, Inc.
1717 West Collins Drive
Orange, CA 92656
Colleen Boswell - Contact Person

MAY - 9 2008

Date Summary Prepared: February 2008

Device Name:

- Trade Name - *Leica FL800*
- Common Name - Fluorescent Angiographic System
- Classification Name - System, X-ray, Angiographic per 21 CFR 892.1600

Devices for Which Substantial Equivalence is Claimed:

- Leica Microsystems, Inc., *Leica FL800 (K061871)*.
- Novadaq Technologies, Inc., *SPY Imaging System (K071037 and K072222)*.

Device Description:

The Leica FL800 device is an accessory to the Leica surgical microscopes. It allows the surgical microscope to produce excitation light and resolve fluorescence light from the fluorescent agent ICG. The generated fluorescence signal depicts the distribution of the infrared dye in the patient's blood vessels during the operation (fluorescence video angiography).

Intended Use of the Device:

The *Leica FL800* is a surgical microscope accessory used in viewing bypass grafts during coronary artery bypass (CABG) surgery, as well as blood flow during plastic and reconstructive surgery.

Substantial Equivalence:

The Leica FL800 is an existing device which was granted market clearance by the FDA following the submission of a 510(k) pre-market notification (K061871). Leica Microsystems seeks only an extension of use into coronary vascular and bypass surgery, as well as plastic and reconstructive surgery. There will be no change to the device design, function or technical characteristics.

The *Leica FL800* is substantially equivalent in intended use, indications and technical characteristics as the *Spy Imaging System*.

Section IV – Substantial Equivalence

The table on the following page compares the *Leica FL800* to two (2) other legally marketed Class II devices which were granted marketing clearance by FDA following the submission of a 510(k) pre-market notification. The 510(k) numbers for the predicate devices are the following:

- *Leica FL800* – 510(k) No. K061871 dated September 20, 2006.
- *Spy Imaging System* – 510(k) No. K071037 dated May 10, 2007 and K072222 dated September 7, 2007.

The Leica FL800 is an existing device which was granted market clearance by the FDA following the submission of a 510(k) pre-market notification. Leica Microsystems seeks only an extension of use into coronary vascular and bypass surgery, as well as plastic and reconstructive surgery.

Representative labeling for the *Spy Imaging System* to which equivalence is being claimed is also included on the following pages. The *Leica FL800* is substantially equivalent in intended use, indications and technical characteristics as the *Spy Imaging System*.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Leica Microsystems (Schweiz) AG
% Sybron Dental Specialties, Inc.
Ms. Colleen Boswell
Regulatory Affairs
1717 W. Collins Avenue
Orange, California 92867

MAY - 9 2008

Re: K080612

Trade/Device Name: Leica FL800
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI
Dated: February 22, 2008
Received: March 4, 2008

Dear Ms. Boswell:

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

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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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,



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

Enclosure

Indications for Use

510(k) Number (if known): K 080612

Device Name: Leica FL800

Indications for Use:

The *Leica FL800* is a surgical microscope accessory used in viewing bypass grafts during coronary artery bypass (CABG) surgery, as well as blood flow during plastic and reconstructive surgery.

Prescription Use

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 CDRII, Office of Device Evaluation (ODE)

Neil R. Ogle, Sr. M.D.
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

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510(k) Number K080612