SECTION 5
510(k) SUMMARY (CONT.)

510(k) Notification K_____

GENERAL INFORMATION

APR 22 2009

Applicant:
Invuity, Inc.
39 Stillman Street
San Francisco, CA 94107
USA
Phone: 1-866-711-7768
FAX: (415) 778-0810

Contact Person:
Kit Cariquitan
Sr. Director, Regulatory and Clinical Affairs
Experien Group, Inc.
155-A Moffett Park Dr., Suite 210
Sunnyvale, CA 94089
USA
Phone: 408-400-0856
FAX: 408-400-0865

Date Prepared: January 9, 2009

DEVICE INFORMATION

Classification:
Surgical Lamp, 21 CFR§878.4580, Class II

Product Code:
FST

Trade Name:
Invuity BriteField™ McCulloch Retractor System

Generic/Common Name:
Light, Surgical, Fiberoptic

SECTION 5
510(k) SUMMARY (CONT.)

PREDICATE DEVICE

Invuity, Inc. believes that the Invuity BriteField™ McCulloch Retractor System is substantially equivalent to the following predicate devices:

- Thompson Lite Wand II, K080962
- Medtronic MAST Quadrant Retractor System, K043602
- Zimmer MIS Light, K080367
- NuVasive MaXcess Light Guide, K042034

INTENDED USE

The Invuity BriteField™ McCulloch Retractor System is intended to provide surgical site illumination from a high intensity light source.

PRODUCT DESCRIPTION

The Invuity BriteField™ McCulloch Retractor System is a blade-based retraction system designed to provide surgeons with the ability to retract tissue through any combination of blades and hooks, when these devices are assembled onto a retractor frame. The Invuity BriteField™ McCulloch Retractor System is similar in design and function to current existing McCulloch Retractor Systems (Class I Exempt) with the exception that it features optional accessory illumination devices (waveguides) that can be attached to the Invuity BriteField™ McCulloch Retractor System's blades and hooks.

The BriteField McCulloch Waveguides are designed to deliver light from any hospital-provided ACMI compatible 300-watt surgical light source via fiber optic cables to a targeted output area in the surgical field. BriteField McCulloch Retractor components and fiber optic cables of the Invuity BriteField™ McCulloch Retractor System are reusable and supplied non-sterile. BriteField McCulloch Waveguides are single-use devices which are provided sterile.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate devices are substantially equivalent to the proposed indications for use for the Invuity BriteField™ McCulloch Retractor System. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the Invuity BriteField™ McCulloch Retractor System is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench and cadaver testing was conducted on the Invuity BriteField™ McCulloch Retractor System to support a determination of substantial equivalence to the predicate devices.

SUMMARY

The Invuity BriteField™ McCulloch Retractor System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2009

Invuity, Inc
% Experien Group, LLC
Mr. Kit Cariquitan
155-A Moffet Park Drive, Suite 210
Sunnyvale, California 94089

Re: K090070
Trade/Device Name: Invuity BriteField™ McCulloch Retractor System
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FST
Dated: April 8, 2009
Received: April 9, 2009

Dear Mr. Cariquitan:

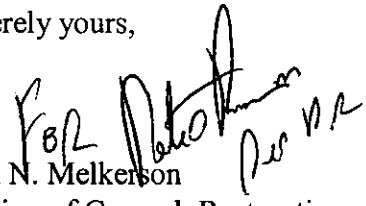
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Invuity BriteField™ McCulloch Retractor System

Indications For Use:
The Invuity BriteField™ McCulloch Retractor System is intended to provide surgical site illumination from a high intensity light source.

Prescription Use _X_ And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mkm
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090070