SURGICeye

Vision for Tomorrow's Surgery

MAR 2 2 2011

# 510(K) Summary < Revised in S2 >
# Confident Surgery Suite 300 (CSS300)

## General information

**510(K) number:** K101887
**Owner's name:** SurgicEye GmbH
**Address:** Friedenstr. 18A, 81671 München, GERMANY
**Phone:** +49 89 5499890 11
**Fax number:** +49 89 5499890 90
**Name of contact person:** Dr. Joerg Traub
**Date:** 18th Dec 2011

**Name of device:** Confident Surgery Suite 300 (CSS300)
**System trade name:** Confident Surgery Suite
**Common name:** Extension of nuclear uptake probe
**Classification name:** Nuclear uptake probe, Class I. 21 CFR § 892.1320 (2010)

## Predicated Devices

**Product:** Neoprobe Model 1500 Portable Radioisotope Detector and Accessories
**Manufacturer:** Neoprobe Corporation
**510(k) number:** K971167

**Substantial Equivalence Date:** 1997/6/26
**Product:** SI-Handheld Gamma Finder (HGF)
**Manufacturer:** Silicon Instruments, GmbH
**510(k) number:** K013751
**Substantial Equivalence Date:** 2002/2/6

**Product:** VectorVision2
**Manufacturer:** Brainlab, AG
**510(k) number:** K983831
**Substantial Equivalence Date:** 1999/05/19

**Product:** Nexstim Eximia navigated brain stimulation system
**Manufacturer:** Nexstim, OY
**510(k) number:** K091457
**Substantial Equivalence Date:** 2009/12/08

## Description

CSS300 is an extension for nuclear uptake detectors designed to obtain 3D images from small organs and structures labeled using radionuclides emitting gamma rays by acquiring data while moving freely with the hand the said detectors.

Examples of nuclear uptake detectors compatible with CSS300 are the nuclear uptake detectors by Crystal Photonics.

CSS300 includes also analysis and display equipment, an optical camera, a cart and an ergonomic arm which allows positioning the required positioning sensor and camera in a suitable position while using the device.

## Indications for Use

Confident Surgery Suite 300 (CSS300) works in conjunction with a nuclear uptake detector capable of measuring the amount of radionuclide taken up by a particular organ or body region. CSS300 is intended to extend the said detector and generate images of the distribution of radionuclides in the human body by means of tracking technologies and image reconstruction techniques. CSS300 extends currently all nuclear uptake detectors by Crystal Photonics. CSS300 may also be used intraoperatively or on pathological specimens if a protective sheath is used to cover the nuclear uptake detector. CSS300 may be used at the patient's bedside, or in an Emergency Room or Intensive Care Unit. The generated images can be used also for documentation and reporting. The interpretation and use of the images generated is intended to be done by trained personnel.

## Substantially Equivalence Claim

CSS300 has the same intended use as the legally marketed predicated devices Neoprobe Model 1500 Portable Radioisotope Detector and Accessories (Neoprobe Corporation), K971167, and SI-Handheld Gamma Finder (Silicon Instruments GmbH), K013751. CSS300 extends a nuclear uptake probe like said predicated devices by further incorporating an infrared tracking system substantially equivalent to the ones included in the cleared VectorVision2 (Brainlab AG), K983831 and Nexstim Eximia Navigated Brain Stimulation System (Nexstim OY), K091457. By combining both technologies and image reconstruction technique, CSS300 is capable of generating images of the radioactivity taken up by a particular organ or body region. CSS300 can be considered an extension to nuclear uptake detectors that make their use more intuitive and thus enable better patient treatment.

CSS300 is as safe and effective as the above-mentioned predicated devices. It meets safety requirements, EN 60601-1: Medical Electrical Equipment – Part 1: General Requirements for Safety, UL 60601-1: Medical Electrical Equipment – Part 1: General Requirements for Safety and EN 60601-1-2:2007: Medical Electrical Equipment – Part 1-2: General Requirements for Safety. Collateral

standard: Electromagnetic compatibility. It bears the CE mark in accordance to the Medical Device Directive 93/42/EEC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. Moritz Hoyer
QM & Regulatory Affairs
SurgicEye GmbH
Friedenstrabe, 18a
D-81671 Munich
GERMANY

MAR 2 2 2011

Re: K101887
Trade/Device Name: CSS300
Regulation Number: 21 CFR 892.1320
Regulation Name: Nuclear uptake probe
Regulatory Class: I
Product Code: IZD
Dated: January 20, 2011
Received: February 8, 2011

Dear Mr. Hoyer:

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

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

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): **K101887**

Device Name: **CSS300**

Indications for Use:

Confident Surgery Suite 300 (CSS300) works in conjunction with a nuclear uptake detector capable of measuring the amount of radionuclide taken up by a particular organ or body region. CSS300 is intended to extend the said detector and generate images of the distribution of radionuclides in the human body by means of tracking technologies and image reconstruction techniques. CSS300 extends currently all nuclear uptake detectors by Crystal Photonics. CSS300 may also be used intraoperatively or on pathological specimens if a protective sheath is used to cover the nuclear uptake detector. CSS300 may be used at the patient's bedside, or in an Emergency Room or Intensive Care Unit. The generated images can be used also for documentation and reporting. The interpretation and use of the images generated is intended to be done by trained personnel.

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 In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101887