

5. 510(k) SUMMARY

SEP 22 2010

510(k) Summary for UROSTATION – 3D PROSTATE SUITE

The 510(k) summary is submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Owner:	KOELIS 5, avenue du Grand Sablon 38700 La Tronche FRANCE Phone: +33 476 637 588 Fax: +33 476 549.561
Contact Name:	Cécile DESMULIE Mail: cecile.desmulie@koelis.com
Date Prepared:	03/17/2010

Proposed Device:

Trade Name:	UROSTATION - 3D PROSTATE SUITE
Common Name:	Medical Image Processing Software System
Classification Name:	System, Image processing, Radiological Picture archiving and communication system, 21 CFR PART 892.2050
Device Class:	II
Product Code:	LLZ

Predicate Device:

The Urostation system is substantially equivalent to:

510(k) Number:	Device Name:
K081093	3-D Imaging Workstation

Intended Use:

UROSTATION - 3D PROSTATE SUITE is a computer-based software application intended to process, visualize and record 3D digital ultrasound images of the prostate.

Indications for Use:

UROSTATION - 3D PROSTATE SUITE is intended to be used by physicians in the clinic or hospital for 2D and 3D visualization of ultrasound images of the prostate gland. Additional software features include patient data management, multi-planar reconstruction and 3D image registration.

Device Description:

UROSTATION - 3D PROSTATE SUITE is a computer-based software application designed to process, visualize and record 3D digital ultrasound images of the prostate, and to manage patient and clinical data in the context of transrectal prostate biopsy.

Hardware Platform and Operating System

The application runs on standard Intel PCs under Microsoft Windows® XP operating system.

Peripheral and accessories

The application is controlled by a footswitch and a manual input device. It is designed to work with commercially available 3D ultrasound scanner through Ethernet connection, 3D transrectal ultrasound probe and needle guide.

Software Features

UROSTATION - 3D PROSTATE SUITE implements image fusion and display algorithms to provide 3D representation of prostate biopsies.

A typical workflow enables the physician to intraoperatively visualize the 3D mapping of biopsies with respect to a reference image of the patient's prostate.

For that purpose, 3D digital images may be transferred at any time from the 3D ultrasound scanner to the Urostation for process and display, while the physician keeps track of the organ using the usual 2D live ultrasound mode.

Alternatively, UROSTATION - 3D PROSTATE SUITE also provides a review mode that allows the mapping of histologic results on the said 3D representation of the patient's prostate. Patient information, images and 3D biopsy cartography may be stored or printed for future retrieval and examination.

Technological Characteristics compared with the predicate device:

UROSTATION - 3D PROSTATE SUITE utilizes the same technological characteristics as the predicate device.

- Both are PC-based software applications that provide 2D/3D medical image acquisition and visualization for enhanced observation and analysis of the prostate gland.
- Both devices provide in addition patient and clinical data management features.
- Both deal with ultrasound images received from commercially available imaging devices.

UROSTATION - 3D PROSTATE SUITE also presents differences with the predicate device. These differences do not raise any safety or effectiveness concern.

- The software architecture follows a linear workflow adapted to the physician's practice.
- The system implements a dedicated algorithm to visualize biopsies with respect to a single reference image of the prostate.
- The system has no measurement features.

Substantial Equivalence Comparison Chart

Company:	KOELIS	EIGEN LLC
System:	3D PROSTATE SUITE	3-D Imaging Workstation
510(k) number:		K081093
Function:	<ul style="list-style-type: none"> ▪ 2D/3D image <ul style="list-style-type: none"> - acquisition - viewing/reviewing - processing - storage ▪ Multi-Planar Reformatting (MPR) ▪ Patient and clinical data management 	
Function:	<ul style="list-style-type: none"> ▪ Printing 	<ul style="list-style-type: none"> ▪ Volume rendering ▪ Segmentation ▪ Measurements
Intended Use:	Process, visualize and record 3D digital ultrasound images of the prostate	
Data Source:	3D TRUS scanners	
Physical Characterization:	Software package - operates on off the shelf hardware - Windows operating system	

Conclusion:

The results of comparing the intended uses, functions and technological characteristics of the UROSTATION - 3D PROSTATE SUITE with its predicate devices shows that the system is as safe and as effective as its predicate device.

Therefore the UROSTATION - 3D PROSTATE SUITE is substantially equivalent to existing products currently on the market.



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

Mr. Cecile Desmulie
Quality Manager
KOELIS
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La Tronche 38700
FRANCE

SEP 22 2010

Re: K100793
Trade Name: Urostation-3D Prostate Suite
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 17, 2010
Received: September 20, 2010

Dear Mr. Desmulie:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

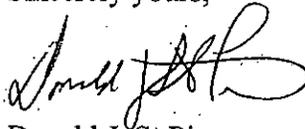
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

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,



Donald J. St. Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

K100793

510(k) Number (if known): Unknown

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Indications For Use:

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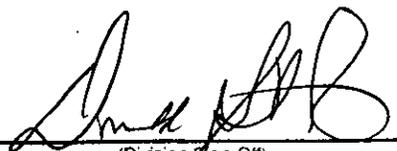
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 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 Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K100793