K053610

510(k) Summary of Safety and Effectiveness for ABARIS

APR 19 2006

I. Manufacturer

Traxtal Technologies Inc.
49 Spadina Ave. Suite 402C
Toronto, Ontario
Canada M5V2J1

II. Contact Person

Dr. Neil Glossop, President
Traxtal Technologies Inc.
Tel: 416-603-8349
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III. Product Name/Classification Name

Product Name:	**ABARIS**
Common Name:	**Computer assisted, image-guided surgery system**
Classification Name:	**Computed Tomography X-ray System**
	Class II as described in 21 CFR 892.1750
Product Code:	**JAK**

IV. Date Prepared

December 19, 2005.

V. Device Description

The ABARIS is a computer assisted, image guided surgery system. It guides a surgical instrument to a target that has been defined by the physician. The target can be indicated either preoperatively or intraoperatively using images or relative to an indicated position on the patient.

The ABARIS provides real-time, three-dimensional visualization and navigation tools for all stages of surgery including preoperative planning and intra-operative navigation. ABARIS transforms two-dimensional patient images (scan sets), derived from Computed Tomography (CT), Magnetic Resonance Imaging (MR), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Ultrasound (US), Fluoroscopy etc. into dynamic representations on which a tool can be navigated. The system performs spatial mapping from one image space to another image space or from image space to physical space ("registration") allowing the physician to correlate scan sets with each other and to the patient. The system facilitates minimally invasive surgical procedures. Like other commercially available image guided surgery systems, the ABARIS also offers computer assisted image-free and registration free navigation using the same instrumentation.

Targeted use areas for ABARIS include hospital operating rooms, outpatient surgery centers and procedure rooms.

VI. Intended Use

ABARIS is a stereotaxic accessory for Computed Tomography (CT), Magnetic Resonance, (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Fluoroscopy, Endoscopy and other imaging systems. It displays the simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organs and the current and the projected future path of the interventional instrument taking into account movements of the patient. This is intended for treatment planning and intra-operative guidance for surgical procedures. The device also supports an image-free mode in which the proximity of the interventional device is displayed relative to another device.

The device is intended to be used in clinical interventions and for anatomical structures where imaging is currently used for visualizing such procedures. The device is also intended for use in clinical interventions to determine the proximity of one device relative to another.

VII. Substantial Equivalence

The technological characteristics of the ABARIS are the same or similar to those found in the predicate devices. The ABARIS is substantially equivalent to the following four FDA cleared frameless stereotaxic systems:

System Name	Manufacturer	510(k) approval number
Ultraguide	Ultraguide Ltd.	K023227, K022354, K013150, K011418, K002258, K974432
StealthStation System	Medtronic Navigation, Inc.	K050438, K043088, K030552, K030106, K022126, K021980, K022414, K020338, K012937, K003201, K001284, K992461, K992927, K990214, K983670, K983397, K981768, K981686, K981684, K974187, K974161, K972398, K963173, K954276
CBYON Surgical Operating System	Cbyon, Inc.	K000171, K012886
Instatrak	GE Medical Systems Navigation and Visualization	K960330, K981998, K982994, K983529, K994270,K003510, K040050

The device labeling contains instructions for use. It includes indications for use, cautions, contraindications, warnings, and planning guidance. This information assures safe and effective use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 19 2006

Neil Glossop, Ph.D.
President
Traxtal Technologies
49 Spadina Avenue, Suite 402C
Toronto, Ontario, M5V 2J1
CANADA

Re: K053610
Trade/Device Name: ABARIS
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 24, 2006
Received: March 27, 2006

Dear Dr. Glossop:

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 (Premarket Approval), 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 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Applicant: Traxtal Technologies Inc.

510(k) Number (if known): Not yet assigned K053610

Device Name: ABARIS

Indications for Use:

ABARIS is a stereotaxic accessory for Computed Tomography (CT), Magnetic Resonance, (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Fluoroscopy, Endoscopy and other imaging systems. It displays the simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organs and the current and the projected future path of the interventional instrument taking into account movements of the patient. This is intended for treatment planning and intra-operative guidance for surgical procedures. The device also supports an image-free mode in which the proximity of the interventional device is displayed relative to another device.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801 Subpart D)

OR

Over-The-Counter Use ___ (Per 21 CFR 807 Subpart D)

David A. Lampron

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053610