K990919

APR 15 1999

Attachment 4

510(k) SUMMARY

1. **Date Prepared**
   March 12, 1999

2. **Submitter (Contact)**
   Peter Ohanian
   Visualization Technology, Inc.
   Wilmington, MA 01887
   (978) 933-1000

3. **Device Name**

Proprietary Name:	The following names are proposed and may be subject to change: Straight Aspirator, 90 Degree Aspirator, 45 Degree Aspirator, 7 French Aspirator, Extended Straight Aspirator, 13.9 cm Straight Pointer, 4.7 cm Aspirator (Note: the above are all accessories of the InstaTrak 3000 K983529.)
Common Name(s):	Aspirators and pointers
Classification Name:	The aspirators and pointers are accessories of the InstaTrak 3000, which is classified as a **Computer tomography x-ray system**.

4. **Device Classification**
   Computer tomography x-ray system (Product Code 90 LLZ, Class II; 21 CFR 892.1750)

5. **Device Description**
   The aspirators and pointers described above are aspiration and/or localization devices supplied as accessories with the InstaTrak 3000 System. The aspirators and pointers have the same principle of operation, as those accessories described in the predicates, K960330, K981998, K982994, and K983529. Other than the non-sterile reusable labeling and a color change to a non-patient contact portion of the instrument the devices are the same as the predicate.

6. **Intended Use**
   The aspirators and pointers have the same intended use as the accessories in the InstaTrak 3000, K983529.

   The InstaTrak 3000 System is intended as an aid to the surgeon for precisely locating anatomical structures anywhere on the human body during either open or percutaneous procedures. It is indicated for any medical condition that may benefit from the use of stereotactic surgery and which provides a reference to rigid anatomical structures such as sinus, skull, cranial, a long bone or vertebra, visible on medical images such as CT or MR.

7. **Substantial Equivalence**
   The predicate devices described in K960330, K981998, K982994, and K983529 have the same intended use, use the same operating principle, incorporate the same design and materials, and allow for sterilization. In summary, the aspirators and pointers in this submission are, in our opinion, substantially equivalent to the predicate devices.

8. **Technological Characteristics**
   The technological characteristics of the aspirators and pointers are identical to those of the predicate devices.

9. **Performance Data**
   Testing was performed on the aspirators and pointers to demonstrate their ability to be cleaned and sterilized and to confirm functionality after multiple reuse cycles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 1999

Peter Ohanian
VP Regulatory Affairs & Quality Assurance
Visualization Technology, Inc.
200 Research Drive
Wilmington, MA 01887

Re: K990919
Straight Aspirator , 45 Degree Aspirator, 90 Degree Aspirator, 7 French Aspirator, Extended Straight Aspirator, 13.9 cm Straight Pointer and 4.7 cm Straight Pointer
Dated: March 17, 1999
Received: March 18, 1999
Regulatory class: II
21 CFR 892.1750/Procode: 90 LLZ

Dear Mr. Ohanian:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510 (k) Number (if known)	K990919
Device Name	Straight Aspirator, 45 Degree Aspirator, 90 Degree Aspirator, 7 French Aspirator, Extended Straight Aspirator, 13.9 cm Straight Pointer, and 4.7 cm Straight Pointer
Indications for Use	The aspirators and pointers are accessories of the previously cleared InstaTrak 3000 System, (K983529) and therefore have the same intended use. The InstaTrak 3000 System is intended as an aid to the surgeon for precisely locating anatomical structures anywhere on the human body during either open or percutaneous procedures. It is indicated for any medical condition that may benefit from the use of stereotactic surgery and which provides a reference to rigid anatomical structures such as sinus, skull, cranial, a long bone or vertebra, visible on medical images such as CT or MR.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990919

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)