NOV 22 1999

K993501

510(k) Summary

3D1 Micropositioning Headstage

Common/Classification Name: Stereotactic Instrument, 21 CFR 882.4560

Scientific Tools, Inc.
2932 Ross Clark Circle, #165
Dothan, AL 36301

334-708-0653
334-702-0653

Contact: Doug Real, Prepared: September 17, 1999

A. LEGALLY MARKETED PREDICATE DEVICES

The **3D1 Micropositioning Headstage** is an accessory to currently marketed stereotactic headframes, which are Class II devices under the responsibility of the Neurological Devices Panel. FDA has assigned the product code 84HAW to stereotactic instruments.

B. DEVICE DESCRIPTION

The **3D1 Micropositioning Headstage** is a device that allows for precise positioning of a neurosurgical instrument along three axes. The device is used in neurosurgical procedures in conjunction with a conventional stereotactic head frame and serves as an accessory to those devices. The **3D1** device comes with a mounting adaptor that is specific for the particular stereotactic head frame being used.

C. INTENDED USE

The **3D1 Micropositioning Headstage** is indicated for use by a qualified neurosurgeon when precise movement of a surgical instrument is needed along any of three axes. The 3D1 Micropositioning Headstage is intended to be used with a standard stereotactic headframe system.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **3D1 Micropositioning Headstage** is a medical device, and it has similar, though slightly different, indications for use as the legally marketed predicate devices. However, the differences do not alter

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the intended therapeutic effect. The **3D1 Micropositioning Headstage** has the same technological characteristics as the predicate devices for which it is an accessory. This premarket notification has described the characteristics of the **3D1 Micropositioning Headstage** in sufficient detail to assure substantial equivalence. In summary, this pre-market submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

E. TECHNOLOGICAL CHARACTERISTICS

Both the **3D1 Micropositioning Headstage** and the predicate devices employ precision mechanical positioning systems to guide neurosurgical instruments. Both the **3D1 Micropositioning Headstage** and the predicate devices are purely manually operated and serve as an aid in positioning to the neurosurgeon.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Scientific Tools, Inc.
c/o T. Whit Athey, Ph.D.
C. L. McIntosh & Associates
12300 Twinbrook Parkway
Suite 625
Rockville, Maryland 20852

Re: K993501
Trade Name: 3D1 Micro Positioning Headstage
Regulatory Class: II
Product Code: HAW
Dated: October 14, 1999
Received: October 15, 1999

Dear Dr. Athey:

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 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 requirement, 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) 594-4595. 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/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K993501

Device Name: **3D1 Micropositioning Headstage**

Indications For Use:

The 3D1 Micropositioning Headstage is indicated for use by a qualified neurosurgeon when precise movement of a surgical instrument is needed along any of three axes. The 3D1 Micropositioning Headstage is intended to be used with a standard stereotactic headframe system.

(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 General Restorative Devices
510(k) Number K993501

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