DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 1997

Ms. Pauline Tao
General Manager
TAO & TAO Technology, Incorporated
957 Ashton Place
Carmel, Indiana 46033

Re: K972496
Trade Name: TAO ASPIRATOR™ and PLASTIC FINGER™
Regulatory Class: II
Product Code: KNW
Dated: September 29, 1997
Received: October 1, 1997

Dear Ms. Tao:

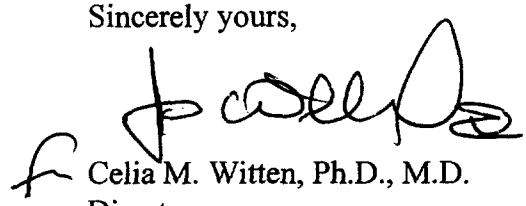
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number: K972496

Device Name: TAO ASPIRATOR™ and PLASTIC FINGER™

INDICATIONS FOR USE:

The TAO ASPIRATOR™ is a device to hold a 10cc syringe for performing fine needle aspiration of a palpable mass with one hand, while stabilizing the mass to be aspirated with the other hand. It is equipped with a release button for automatically drawing back the syringe plunger, and is designed to be held in a pencil-grip manner. This device places the hand relatively close to the needle tip while the hand is in a position of natural function, enabling the needle movement using fine motor control of the hand.

The PLASTIC FINGER™ is an accessory to the TAO ASPIRATOR™ to facilitate specimen procurement. It facilitates needle removal so that air can be drawn into the syringe, and the aspirated material in the needle and needle hub can then be expressed onto slides. It can also be used to grip slides for fixation and staining.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972496

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CPR 801.109)

(Optional Format 1-2-96)