DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 16 1998

Mr. John R. Miers
Director of Regulatory Affairs
AccuMed International, Inc.
900 N. Franklin, Suite 401
Chicago, Illinois 60610

Re: K982786
Trade Name: TracCell™ 2000 Slide Mapping System
Regulatory Class: II
Product Code: JOY
Dated: August 7, 1998
Received: August 10, 1998

Dear Mr. Miers:

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) 594-4588. 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~K954698~~ K982786

Predicate Device Name: TracCell™ 2000 Slide Mapping System

Indications For Use:

The new TracCell™ 2000 Slide Mapping System is intended as a computer-aided Slide Mapping System integrated to an automated optical microscope workstation (AccuMed International's AcCell™ Workstation). The TracCell™ 2000 Slide Mapping System is used to map adequately stained, well-preserved, cervical cytology preparations that have been prepared using a Papanicolaou or Pap-like stained protocol. In addition to the present intended use as cleared by FDA, the new TracCell™ 2000 Slide Mapping System can be used for the purposes of mapping Cytyc ThinPrep® specimens. The mapping of the slide into ìpresentedî and ìexcludedî fields of view is performed by segmenting the light-absorbing objects from background material based upon standard image processing techniques for efficient presentation to a cytotechnologist or cytopathologist for diagnostic interpretation.

1. All cellular material within the expanded cell deposition area, comprising the standard cellular deposition area, and a narrow bleed zone immediately surrounding it, will be presented for human screening, using the minimum number of fields-of-view.

2. All adequately stained, well preserved cells located in the annular ring, the area lying between the expanded cellular deposition area, and the imprinted boundary area and the imprinted boundaries of the slide, will be included in additional fields-of-view presented for human screening.

The mapping of a Cytyc Thin Prep™ specimen is carried out in precisely the same manner as the predicate TracCell 2000 Slide Mapping System. The mapping of the slide in presented and excluded fields-of view, is performed by segmenting the light absorbing objects from background material based upon standard image processing techniques for efficient presentation to a cytotechnologist or cytopathologist for diagnostic interpretation. These techniques are identical to the predicate TracCell 2000™.

(PLEASE DO NOT WRITE BELOW THIS TEXT - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Deborah Moore
for Dr. Peter Maxim
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982786