

MAY 16 2000

K993699

ATTACHMENT I

510(K) SUMMARY
Mid-Atlantic Diagnostics, Inc. – “THE STRIPPER®”

This 510(K) Summary of safety and effectiveness for the Mid-Atlantic Diagnostics, Inc. “*THE STRIPPER®*” is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant: Mid-Atlantic Diagnostics, Inc.

Address: 338 Stokes Road
Medford, NJ 08055

Contact Person: Terrance J. Fortino, President

Telephone #: (609) 953-3380

Fax #: (609) 953-3286

Preparation Date: October 29, 1999

Device Trade Name: “*THE STRIPPER®*” Micropipetter and Micropipetter Tips

Common Name: Micropipettes used for IVF

Classification Name: Assisted Reproduction Microtools (per 21 CFR 884.6130)
85-MQH

Substantial Equivalence: Substantial equivalence is being supported by the Federal Register Notice Final Rule entitled “Obstetric and Gynecologic Devices; Reclassification and Classification of Medical Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures. This equivalence is supported by the Summary statement:

Upon the effective date, the Federal Register document may be cited in the absence of an existing predicate device which would be used to support substantial equivalence.

Description of Mid-Atlantic Diagnostics, Inc. “THE STRIPPER®:

“**THE STRIPPER®**” micropipetter is a hand held device used to create the vacuum necessary for “**THE STRIPPER®**” micropipetter tips to aspirate and dispense fluid and cellular material. Its’ components include an aluminum barrel that houses a stainless steel plunger and spring, an aluminum plunger shaft with finger pad, o-rings, washer and collet for securing “**THE STRIPPER®**” tips.

(See Attachment III – “**THE STRIPPER®**” Spec Sheet)

“**THE STRIPPER®**” micropipette tips are fabricated from polycarbonate tubing wherein one end of the tube is pulled to a much smaller dimension to produce tips of varying internal dimensions.

Testing Procedures:

Each lot of micropipettes is mouse embryo tested for toxicity using a one-cell mouse embryo bioassay. The assay is performed utilizing freshly collected embryos and culturing them in HTF medium supplemented with 0.4% BSA which was exposed to the test article. The extracted test media and non-extracted HTF medium (control) is placed in a culture dish in triplicate microdrops and overlaid with light mineral oil. The dish is allowed to equilibrate in an atmosphere of 5% CO₂ at 30°C for a minimum of 2 hours. Following equilibration, the embryos are added to both the test and control medium and returned to the incubator. Embryo development is noted at 24 and 96 hours. Test articles that score $\geq 70\%$ development to blastocyst at 96 hours are considered non-toxic. A score of $\geq 70\%$ to blastocyst in the control medium indicates a valid assay.

Sterilization is performed by gamma irradiation. The sterilization validation program follows the United States Pharmacopeia 23(71) procedure. It is justified due to a low bioburden and every lot being validated for sterility. The sterility assurance level for the micropipette is 10^{-6} .

The minimum established radiation dose is 15 kGy established by AAMI Method I, SIP. The maximum radiation dose is 25 kGy.

Each lot of micropipettes is also tested for endotoxin levels using the Limulus Amebocyte Lysate assay. The level of endotoxin units per device must be less than 0.03 EU/ml to be considered acceptable.

Intended Use Statement:

“**THE STRIPPER®**” micropipette family’s indication for use is to manipulate and transfer zygotes and embryos during IVF and ICSI procedures.

“**THE STRIPPER®**” micropipettes are used in the tissue culture techniques performed by embryologists when preparing oocytes for IVF, ICSI and assisted hatching techniques prior to re-implantation.

“**THE STRIPPER®**” micropipettes are tools used in procedures that have been developed to aid infertile couples achieve pregnancy.

Performance Standards: Not Applicable

Conclusion: Mid-Atlantic Diagnostics, Inc. “**THE STRIPPER®**” Micropipetter and Micropipette Tips are substantially equivalent to other existing micropipette tools used in the IVF procedure.

Additional Information: None requested at this time

**MAY 16 2000**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. Terrance J. Fortino
President
MidAtlantic Diagnostics, Inc.
338 Stokes Road, Suite E
Medford, NJ 08055Re: K993699
The Stripper® Assisted Reproduction
Microtool
Dated: February 10, 2000
Received: February 16, 2000
Regulatory Class: II
21 CFR §884.6130/Procode: 85 MQH

Dear Mr. Fortino:

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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

INDICATION FOR USE STATEMENT

510(K) NUMBER: K 993699

DEVICE NAME: MID-ATLANTIC DIAGNOSTICS, INC.
"THE STRIPPER®"

INDICATIONS FOR USE:

"THE STRIPPER®" MICROPIPET FAMILY'S INDICATION FOR USE IS TO MANIPULATE AND TRANSFER ZYGOTES AND EMBRYOS DURING IVF AND ICSI PROCEDURES.

"THE STRIPPER®" MICROPIPETS ARE USED IN THE TISSUE CULTURE TECHNIQUES PERFORMED BY EMBRYOLOGISTS WHEN PREPARING OOCYTES FOR IVF, ICSI AND ASSISTED HATCHING TECHNIQUES PRIOR TO RE-IMPLANTATION.

"THE STRIPPER®" MICROPIPETS ARE TOOLS USED IN PROCEDURES THAT HAVE BEEN DEVELOPED TO AID INFERTILE COUPLES ACHIEVE PREGNANCY.

REMOVES CUMULUS AND CORONA CELLS FROM OOCYTE FOR CONFIRMATION OF FERTILITY DURING IVF.

REMOVES CUMULUS AND CORONA CELLS FROM OOCYTE PRIOR TO ICSI PROCEDURES.

USED TO TRANSFER EMBRYOS AND OOCYTES THROUGH VARIOUS MEDIA AND SOLUTIONS DURING THE IVF PROCEDURE.

(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 801.109)

OR

OVER THE COUNTER USE

David G. Ferguson
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K 993699