

OCT - 9 1997

510(k) SUMMARY
Diamedix's MAGO™ Automated EIA Processor

←973177

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared:**

Submitter and Contact Person's Name:

Lynne Stirling, Ph.D.
Diamedix Corporation
2140 North Miami Avenue
Miami, FL 33127
Phone: (305) 324-2354
Facsimile: (305) 324-2585

Date Prepared: August 21, 1997

Name of Device and Name/Address of Sponsor

Name of Device: MAGO™ Automated EIA Processor

Name and Address of Sponsor:

Lynne Stirling, Ph.D.
Diamedix Corporation
2140 North Miami Avenue
Miami, FL 33127
Phone: (305) 324-2354
Facsimile: (305) 324-2585

Common or Usual Name

Automated EIA Processor

Classification Name

Pipetting and diluting system for clinical use

Predicate Devices

(1) Rosys Plato 3300

000100

Technological Characteristics and Substantial Equivalence

Intended Use:

The MAGO is intended to be used as a general purpose automated EIA processor. The MAGO is indicated for use in moderate complexity laboratories for performing automated EIA procedures.

Principles of Operation:

The MAGO and its predicates all share the same principle of operation. Each device provides a pipetting station which is capable of performing normal pipetting functions such as, accurately aspirating and dispensing fluids into microplates and a wash station capable of simulating a microplate washing device. The device allows user programming which controls the sequence of activity to allow sample dilution and addition, incubation, and reagent dispensing which mimics and duplicates manual assay procedures.

Technical Characteristics:

The MAGO and the predicate processors employ an automatic transport mechanism to bring the individual microplate into position for processing. All the devices employ standard pipetting and washing technology to perform the various processing procedures.

Performance Data:

The MAGO was compared to the standard manual procedures in six separate EIA systems. In all instances, the MAGO functioned as intended and demonstrated that there was no substantial difference between performing the test manually and performing the assay on the MAGO.

Summary of the Basis for the Finding of Substantial Equivalence:

The MAGO is substantially equivalent to the other currently marketed devices and to the manual methods which are referenced above. There is no substantial difference between the MAGO and its predicate devices in performance or technical characteristics. The MAGO has the same intended use, indications for use, and the same principles of operation as the predicate devices. Thus, the MAGO raises no new issues of safety or effectiveness.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 9 1997

Lynne Stirling, Ph.D.
Diamedix Corporation
2140 North Miami Avenue
Miami, Florida 33127

Re: K973177
Trade Name: MAGO™ Automated EIA Processor
Regulatory Class: II
Product Code: JJF
Dated: August 21, 1997
Received: August 25, 1997

Dear Dr. Stirling:

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 (Pre-market 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 pre-market 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.

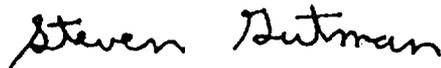
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,



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

INDICATIONS FOR USE STATEMENT

510(K) Number: K973177

Device Name: MAGOTM Automated EIA Processor

Indications for Use:

The Diamedix MAGO is indicated for use as a general purpose automated EIA processor for use in clinical laboratories.

**PLEASE DO NOT WRITE BELOW THIS LINE
ANOTHER PAGE IF NEEDED)**

(CONTINUE ON

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K973177