K980120
Feb. 6, 1998

DIGENE
9000 Virginia Manor Road
Beltsville, Maryland 20705
(301) 470-6500
FAX (301) 470-6498

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:_____.

Submitter's Name, Address, Telephone and Facsimile Numbers, Contact Person, and Date Prepared:

Submitter
Digene Corporation
9000 Virginia Manor Road, Suite 207
Beltsville, MD 20705
Phone: 301-470-6500
Facsimile: 301-470-2881

Contact Person
Constance A. Finch, Dr.P.H.
Director of Regulatory and Clinical Affairs
Digene Corporation
Phone: 301-470-6557
Facsimile: 301-470-2881

Date Prepared: January 12, 1998

Trade Name: Digene DML 2000™ Microplate Luminometer

Common or Usual Name: Luminometer

Classification Name: Colorimeter, photometer, or spectrophotometer for clinical use

Predicate Device: MLX Microtiter® Plate Luminometer (K962265)
Dynatech Laboratories

DIGENE
9000 Virginia Manor Road
Beltsville, Maryland 20705
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Device Description:

The DML 2000 is a microplate luminometer capable of reading chemiluminescence from opaque microplates. Chemiluminescence is the production of light from a chemical reaction. The luminometer is optimally designed for measurement of glow type luminescence. The luminometer is designed to be run and controlled by a personal computer connected via a serial RS-232 interface port. The instrument is simple in design with measurement taking place in 96-well microplates, where each well is presented to the detector by stepper motors moving the plate. The light is detected by a photomultiplier tube. The light is amplified and converted to an electrical signal which is detected by a sensitive electrical amplifier. The detected signals are converted to Relative Light Units (RLU) and are reported for each well of the microplate. Assay results are calculated and interpreted according to assay validation parameters.

Intended Use:

The Digene DML 2000 Microplate Luminometer is intended to measure light that is emitted as a result of a chemiluminescent reaction. Assay results obtained using chemiluminescence technology in 96 well microplates are calculated and interpreted according to assay validation parameters.

Technological Characteristics:

The Digene DML 2000 Microplate Luminometer is substantially equivalent in terms of intended use and principles of operation to the MLX® Microtiter Plate Luminometer manufactured by Dynatech Laboratories. Both devices are intended for the measurement of light produced by chemiluminescence. There are no differences in technological features that raise new or different issues regarding safety or effectiveness. The DML 2000 does not have any direct patient contact or otherwise perform any therapeutic patient function. The DML 2000 measures the light produced by chemiluminescent reactions and provides test results in a spreadsheet format.

The Digene software incorporated in the DML 2000 was developed and manufactured in accordance with comprehensive software development, validation and verification procedures.

The DML 2000 conforms to safety and environmental standards relevant to luminometers. A hazard analysis has been performed and all known hazards are adequately addressed by device design or user instructions.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB - 6 1998

Constance A. Finch, Dr.P.H.
Director of Regulatory and Clinical Affairs
Digene Corporation
9000 Virginia Manor Road
Beltsville, Maryland 20705

Re: K980120
Digene DML 2000™ Microplate Luminometer
Regulatory Class: I
Product Code: KHO, JJQ
Dated: January 12, 1998
Received: January 13, 1998

Dear Ms. Finch:

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 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.

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

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INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K980120

Device Name: Digene DML 2000 Microplate Luminometer

Indications for Use: The Digene DML 2000 Microplate Luminometer is intended to measure light that is emitted as a result of a chemiluminescent reaction. Assay results obtained using chemiluminescence technology in 96 well microplates are calculated and interpreted according to assay validation parameters.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Clinical Laboratory Device
510(k) Number K980120