

Segami Corporation

K 97 2 886

10. 510K Summary

OCT - 1 1997

10.1. Identification

10.1.1 Date of Application:

August 4, 1997

10.1.2 Manufacturing Facility:

Segami Corporation, Inc.
12624 Golden Oak Drive
Ellicott City, MD 21042
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10.1.3 Contact Person :

Philippe Briandet Ph.D.
12624 Golden Oak Drive
Ellicott City, MD 21042
phone: (410) 531-2357
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10.1.4 Signature

Philippe Briandet

Date 08-04-97

10.2. Device Name

10.2.1 Classification Name:

Image Processing System

10.2.2 Common/Usual Name:

Nuclear Medicine Planar and SPECT
Image Processing Software

10.2.3 Proprietary Name:

MIRAGE

10.3. Substantial Equivalence (Predicate devices)

The predicate devices are the ICON COMPUTER SYSTEM by Siemens Medical Systems, Inc.(Product code JWM, 510K # K914350) and SOPHY NXT by Sopha Medical Systems, Inc.(product code KPS and 501K# K913641).

Substantial equivalence was shown non-clinically by demonstrating that **Generic Image Operations, Generic Tomographic post-processing, First Pass Ventriculography and Planar Gated Blood-pool Analysis** did not yield substantially different results from those of the predicate devices.

Substantial equivalence was evidenced clinically by demonstrating that in the clinical applications (of current clinical cases or archival cases) the clinician's conclusion would not have differed substantially.

The technological characteristics which differ have no effect on the software's results: The Mirage system is based on the PC architecture (versus Macintosh and proprietary for predicate devices), the operating system is Windows NT (versus Macintosh and Forth), the software language is Visual C++ (versus Pascal and Forth).

The Patient Data Management went through a separate technical test in which the validity and integrity of the data was evaluated.

Conclusion:

The Mirage Software package is closely similar in intended use and technical characteristics to the predicate devices. The product raises no new questions regarding safety or effectiveness. Segami Corporation, Inc. concludes that the product is essentially equivalent to devices of the same classification previously approved.

10.4 Description.

Camera driven acquisition software refers to the formatting of camera signals into spatial distributions, and producing timing signals allowing camera defined acquisition or motion to proceed. The term **processing** refers to all manners of data manipulation, following the acquisition, including the reconstruction of tomographic volume data from multiple projection acquisitions. The term **post-processing** refers to image manipulation and analysis which occurs after the image (planar or tomographic, static or dynamic) has been formed. Post-processing specifically includes **display** methods, which determine how the user can (re)view and interpret the data.

The most crucial component for a post-processing system, which should be able to receive and handle data (images) from different origins (acquisition systems), is the **Patient Data Management**.

The product (**Mirage**) is basically a camera driven acquisition, processing and post-processing (visualization and analysis) software system with a **Patient Data Management** system, to which minimal processing (e.g. tomographic reconstruction) has been added.

10.5 Statement of Indication for use.

The intended use of the Mirage system of image acquisition, processing and analysis is to provide the Nuclear Physician with a tool to acquire, format and store the data acquired by a camera, to display in all the traditional manners, to add three-dimensional renderings to the displays, and to display some kinetic attributes of the imaged organs or systems. The major benefits are the ease of use, the speed of processing, and the variety of display alternatives.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Philippe Briandet, Ph.D.
President
Segami Corporation
12624 Golden Oak Drive
Ellicott City, MD 21042

OCT - 1 1997

Re: K972886
Mirage Nuclear Medicine Image
Processing System
Dated: August 4, 1997
Received: August 5, 1997
Unclassified/Procode: 90 LLZ

Dear Dr. Briandet:

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 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 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) 594-4613. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972886

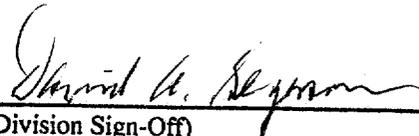
Device Name: Mirage

Indications for Use:

The Mirage system is indicated for the acquisition, formatting and storage of scintigraphy camera output data. It is capable of processing and displaying the acquired information in traditional formats, as well as in pseudo three-dimensional renderings, and in various forms of animated sequences, showing kinetic attributes of the imaged organs.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K972886

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)