DEC 21 1999

K993681

510 (K) SUMMARY

Name:	Digitec Medical Service Corporation
Address:	465 Maltbie Street, Suite 407, Lawrenceville, GA. 30045
Phone:	770-995-0050
Fax:	770-995-8553
Contact person:	James McGinty
Date of preparation:	October 29, 1999
Name of Device:	Digitec Two Stage Compression Kit
Trade:	Digitec Two Stage Compression Kit
Common:	Accessory to Mammography Compression Device
Classification name:	Accessory to Mammographic X-Ray System Per 21 CFR SEC 892.1710

Legally marketed device to which we are claiming equivalence:

The device to which substantial equivalence is being claimed is the GE Senographe 600T and 600Ts. X-ray mammography systems. The 510(k)-document control number for this comparison device is K881882.

Description of Device

The Digitec Two Stage Compression Kit is an accessory item designed for use in the GE Senographe 600T series X-Ray Mammography Systems. It is comprised of two parts:

1) Compression Control Module

The compression control module is a small electrical circuit added to the original compression control system. It modifies the system to give the technologist a smoother method for applying "fine adjustment" compression force.

2) Paddle Leveling Spacers

The leveling spacers are used to change the position of the compression paddles relative to the bucky surface. The spacers are small aluminum pieces designed to fit on the compression paddle mounting arms. The spacers remove the 1.2 degree tilt of the original design and reposition the paddles flat and parallel with the surface of the bucky.

Intended Use of The Digitec Two Stage Compression Kit

The kit is intended to improve the performance of the compression system of the GE Senographe 600T series x-ray mammography systems. It is designed to position the compression paddles flat and parallel with the bucky surface and to give the technologist a smoother method for applying "fine adjustment" compression force.

It is not intended to change the basic operation of the compression system, the operator controls, or the amount of compression force applied to the breast. The kit does not change the compression release features in any way.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 1999

James J. McGinty
Digitec Medical Service Corporation
465 Maltbie Street, Suite 407
Lawrenceville, GA 30045

Re: K993681
Digitec Two Stage Compression Kit
Dated: October 29, 1999
Received: November 1, 1999
Regulatory class: II\
21 CFR 892.1710/Procode: 90 IZH

Dear Mr. McGinty:

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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS OF USE

The Digitec Two Stage Compression Kit is a modification for the GE Senographe 600T series x-ray mammography systems. It modifies two aspects of the compression system.

First, the kit is intended to improve the "fine adjustment" control of the compression sequence. The original design of the compression system uses the same control method for applying initial compression force and for "fine adjustment" force. The kit does not change the method to apply initial compression force. It modifies the control sequence to achieve smoother fine adjustment control. "Fine adjustment" control is required to slowly and incrementally add the last little bit of compression just prior to making the exposure.

The modification kit also repositions the compression paddle to be flat and parallel with the breast support plate. The original design elevates the chestwall edge of the compression paddle off of the breast support plate. The kit removes the 1.2-degree tilt of the original design.

The kit is not intended to change the basic operation of the compression system, the operator controls, or the amount of compression force applied to the breast. Finally, the kit does not change the safety or compression release features in any way.

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993681

Prescription Use ✓
(Per 21 CFR 801.109)