3/10/99

K984466

Section E – 510(k) Summary

I. General Information

A. Submitted By:

Dilon Technologies Inc.
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Contact Person:

Lee H. Fairchild
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B. Device Trade Name: *Dilon 2000*
Common Name: Gamma Camera System
Classification Name: Scintillation (Gamma) Camera

C. Predicate Devices: ADAC Transcam (K924639)

D. Device Description:

The *Dilon 2000* is a high resolution, small field of view, portable gamma camera designed for general use in imaging radio pharmaceuticals.

The primary components of the *Dilon 2000* are:

Detector Head: contains a two dimensional array of scintillation crystals, an array of position sensitive photomultiplier tubes and signal amplification and discrimination electronics.

Gantry Arm: safely supports the detector as positioned by the technologist operating the camera. Counter balancing is provided to hold the detector in its last position.

Mobile Cabinet: Contains data acquisition electronics, image development computer and Segami Pegasus™ imaging software. The cabinet also contains power filtering, isolation and a high voltage power supply.

D. Intended Use:

The *Dilon 2000* Digital Gamma Camera is intended to be used to measure and image the distribution of selected single photon emitting radioisotopes in the human body. The resulting images are intended to be reviewed by qualified medical personnel.

E. Substantial Equivalence:

The *Dilon 2000* has the same indications for use as the predicate gamma cameras and employs equivalent gamma detection technology.

II. Testing

Images and performance testing data were collected on a prototype camera. Image quality and camera usage is equivalent to that of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 1999

Lee H. Fairchild
Director of Product Marketing
Dilon Technologies Inc.
Applied Research Center
12050 Jefferson Ave., Suite 250
Newport News, VA 23606

Re: K984466
Dilon 2000 Gamma Camera
Dated: December 14, 1998
Received: December 16, 1998
Regulatory class: I
21 CFR 892.1100/Procode: 90 IYX

Dear Mr. Fairchild:

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

510(k) Number (if known): K984466
Device Name: Dilon 2000

Nuclear Medicine Devices

Indications For Use: To detect or image the distribution of radionuclides in the body or organ, using the following technique(s).

	YES	NO	Energy Range (keV)
A. Planar Imaging	X		100 to 200
B. Whole body imaging		X	
C. Tomographic imaging (SPECT) for non Positron emitter		X	
D. Positron imaging by coincidence		X	
E. Positron imaging without coincidence		X	
F. Other indication(s) in the device label, but not included in the above list		X	

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

...sion Sign-Off)
...sion of Reproductive, Abdominal, ENT,
...d Radiological Devices
...k) Number K984466

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)