

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. General Information

A. Submitted By: ADAC Laboratories
540 Alder Drive
Milpitas, CA 95035
Tel: (408) 321-9100
Fax: (408) 321-9686

Contact Person: Dennis Henkelman at address above

B. Device Trade Name: Vantage 3.0 InSynch™
Common Name: Gamma Camera Systems
Classification Name: System, Emission Computed Tomography

C. Predicate Device: Vantage 2.0 ExSPECT

D. Device Description:

Vantage 3.0 InSynch™ is a software program, which will be marketed as an optional addition to ADAC Laboratories Gamma Camera products. This is a modification of the Vantage 2.0 ExSPECT software package, cleared in 510(k) K971878.

Vantage 3.0 InSynch™ is a computer program that produces nuclear medicine images of two isotopes acquired simultaneously, corresponding to specific energy levels and a transmission image from external radioactive scanning line sources. Vantage 3.0 InSynch™ is an extension of Vantage 2.0 ExSPECT which acquires a single isotope image with the transmission image produced by the external radioactive scanning line sources.

E. Indications for Use:

The Vantage 3.0 InSynch™ option to the ADAC Gamma Camera Systems is intended to produce images of two emission isotopes simultaneously while also acquiring a transmission image.

F. Technological Comparison:

The Vantage 3.0 InSynch™ and Vantage 2.0 ExSPECT devices have the same source type, source strength, source geometry, system hardware, and operating principles. Whereas the Vantage 2.0 ExSPECT device was intended for the acquisition and reconstruction of a single emission isotope in addition to a line source, the Vantage 3.0 InSynch™ is intended for the acquisition of dual isotopes simultaneously.

II. Testing

A study was conducted to demonstrate that Vantage 3.0 InSynch™ provides comparable images using simultaneous dual-isotope scanning to sequential dual-isotope scanning. The quality of the images produced was similar to the quality of images produced by the predicate device.



JUN 29 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dennis W. Henkelman
Director, Regulatory Affairs and Quality Affairs
ADAC Laboratories
540 Alder Drive
Milpitas, CA 95035

Re: K981291
Vantage 3.0 InSynch™
Dated: April 8, 1998
Received: April 9, 1998
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Henkelman:

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.

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,

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K981291

Device Name: Vantage 3.0 InSynch™

Sponsor Name: ADAC Laboratories

Indications for Use

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
Over-The-Counter Use

David H. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981291