

OCT 29 1998

Page 1 of 2

## 510(k) Summary of Safety and Effectiveness.

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

**Company Name** : Philips Medical Systems North America Company.  
**Address** : 710 Bridgeport Avenue  
Shelton, CT 06484.  
**Registration No.** : 1217116

**Contact person** : Peter Altman  
**Telephone Number** : 203-926-7031

**Prepared** : July 1998.

**Device Name** : **RestGrid** package / GYROSCAN NT.  
**Classification Name** : Magnetic Resonance Diagnostic Device.  
**Classification** : Class II.

**Performance standards** : NEMA voluntary standards, FDA MRI guidances, UL and IEC 601 relevant safety standards and/or draft standards are used.

**Common/Usual Name** : RestGrid/ Tagging studies / SPAMM / CSPAMM

**Predicate Device(s)** : - RestSlab technique Gyroscan NT (ref.K.980645)  
- Cardiac Tagging Techniques / Magnetom Vision (ref.K973799).

### Device Description :

RestGrid is a software option available for the Gyroscan-NT platforms: ACS-NT, T10-NT, T5-NT and the Gyroscan-CV.

RestGrid applies regional saturation of magnetization to the tissue. The saturation is spatially modulated resulting in a series of equally spaced saturation lines or bands. Deformation of the saturation pattern is used to evaluate regional cardiac motion or blood flow.

### Intended Use :

The RestGrid Option on the Gyroscan NT and Gyroscan CV is used to evaluate regional heart wall motion and blood flow in a non-invasive study..

### Technological Characteristics:

The technological characteristics remain identical to other Gyroscan NT systems. Spatially modulated saturation of the magnetization of the tissue is introduced for imposing the patterns of saturation lines.

### General Safety and Effectiveness Concerns

The safety parameters of the MR systems remain the same as with the FDA cleared Gyroscan NT systems (re.K963990) and within the limits of the FDA documents: "Attachment 1 of Guidance for content and review of a magnetic resonance device 510(k) application" and draft "MRI Guidance Update for dB/dt dd. 10-11-'95".

**Substantial Equivalence**

Philips believes the RestGrid Software Package to be substantially equivalent to saturation techniques applied in commercially available RestSlabs (FDA re.K980645) and to Siemens Cardiac Tagging (FDA re.K973799).



OCT 29 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Peter Altman  
Director of Regulatory Affairs  
Philips Medical Systems  
710 Bridgeport Avenue  
Shelton, CT 06484

Re: K982834  
RestGrid Package for Philips Gyroscan  
NT and Gyroscan CV  
Dated: August 11, 1998  
Received: August 12, 1998  
Regulatory class: II  
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Altman:

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

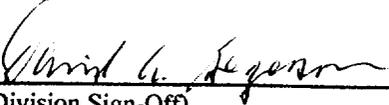
510(k) Number (if known): Unknown  
Device Name : RestGrid package option for GYROSCAN NT and GYROSCAN CV.

Indication For Use :

The **RestGrid** is a software option to the Philips GYROSCAN NT and GYROSCAN CV systems.  
This option is used to evaluate regional heart wall motion in both the left and right side of the heart and blood flow in a non-invasive study.  
The indication for use of the GYROSCAN NT and GYROSCAN CV systems remains the same, i.e. for use as diagnostic devices that produce transverse, sagittal, coronal and oblique cross-sectional images, spectroscopic images and/or spectra, based upon <sup>1</sup>H and <sup>31</sup>P metabolites, and that display the internal structure and/or function of the head, body or extremities. These images and/or spectra when interpreted by a trained physician, yield information that may assist in diagnosis.

( 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 K982834

Prescription Use  OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)