



## Philips Medical Systems

K991765

P.O. Box 10000, 5680 DA Best, The Netherlands

XJB-148-3727/bf  
1999-04-08

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

The following 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

**Device (Trade) Name** : **Synergy Shoulder coil**  
**Classification Name** : Magnetic Resonance Specialty Coil.  
**Classification** : Class II.  
**Product code** : MOS  
**Performance standards** : NEMA voluntary standards, FDA MRDD guidance's, UL and IEC 601 appropriate safety standards and/or draft standards are used.  
**Common/Usual Name** : RF external Synergy Shoulder coil

#### Predicate Device(s).

The Philips RF external E1 flexible coil and other current synergy coils as part of the commercially cleared MRDD Philips GYROSCAN NT Release 6 series systems with FDA ref.K980645.

#### Intended use.

Due to its shape and size the RF external **Synergy Shoulder coil** allows a variety of applications but with the main purpose of optimal imaging of the shoulder structure. It is compatible to be used with the Philips GYROSCAN NT systems which are indicated 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..

#### Device Description and Technological Characteristics

The **Synergy Shoulder coil** is a synergy RF receive only coil which is compatible for use with the MRDD Philips GYROSCAN NT systems. It is designed for a variety of applications but with the main purpose for optimal imaging of the shoulder. The coil consists of a pair of elliptical flexible coil elements (dimensions 14x17cm per element). Two version of the coil will be available, i.e. for the 1.5 Tesla ( 63MHz) and 1.0 Tesla (42MHz) MRDD systems.



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Close to the coil elements the synergy pre-amplifiers and electronic circuitry are mounted in a box which is sealed together with the coil elements. A "bazooka" cable is applied for RF filtering. The "bazooka" cables are fed into a combined (driver) box and connected to MR system (scanner). The Synergy Shoulder coil is an external RF coil made of routinely-used materials. The technological characteristics are based on the same concept as with the other synergy coils which have been cleared as part of the MRDD Philips GYROSCAN NT Release 6 series systems (ref.K980645).

### **General Safety and effectiveness.**

The safety and effectiveness of the Synergy Shoulder coil are the same as with the other current synergy coils which are cleared as part of the GYROSCAN NT Release 6 systems (ref.K980645) It does not induce other safety issues and warnings than already valid for the current cleared RF external coils.

### **Substantial Equivalence.**

The Synergy Shoulder coil is substantially equivalent to the predicate device RF external E1 flexible coil as part of the commercially cleared Philips GYROSCAN NT Release 6 series systems with FDA ref.**K980645**.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG -2 1999

Peter Altman  
Director of Regulatory Affairs  
Philips Medical Systems  
710 Bridgeport Avenue  
Shelton, Connecticut 06484-0917

Re: K991765  
Synergy Shoulder Coil for Gyroscan  
Dated: May 20, 1999  
Received: May 24, 1999  
Regulatory Class: II  
21 CFR 892.1000/Procode: 90 MOS

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 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



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510(k) Number (if known): K991765  
~~Unknown~~  
Device Name : Philips Synergy Shoulder Coil.

### Indication For Use :

Due to its shape and size the RF external **Synergy Shoulder coil** allows a variety of applications but with the main purpose of optimal imaging of the shoulder structure. It is compatible to be used with the Philips GYROSCAN NT systems which are indicated 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)

David A. Seymour  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K991765

Prescription Use   
(Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)