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SISTEMI
MEDICALI

MAR 2 5 2005

K050190

Attachment 1 - 510 (k) SUMMARY

510(k) summary for APOLLO

Identification

Applicant	Villa Sistemi Medicali S.p.A. Via delle Azalee 3, 20090 BUCCINASCO - Milan- Italy Registration Number: 8021091
Contact Person	dr. Roberto Daglio – QA Director
Telephone (applicant)	+ 39 02 48859233
Designated Agent in the US	Veronica Meredith Del Medical Imaging 11550 West King Street Franklin Park Illinois 60131 Tel. 847-288-7000
Manufacturing site	Villa Sistemi Medicali S.p.A. Via delle Azalee 3, 20090 BUCCINASCO - Milan - Italy

Trade name: APOLLO
Common name: APOLLO R/F remote controlled table
Classification:
The equipment is classified as a class II device since it is composed of the following three components:

radiological table (CFR892.1980): class I

spot film device (CFR892.1670): class II

X-ray beam limiting device (CFR 892-1610): class II

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Substantial equivalent device: the APOLLO is defined as Substantially Equivalent (SE) to the Philips Medical Systems OMNIDIAGNOST ELEVA, manufactured by Philips Medical Systems and cleared by FDA with K032046

The following table compares the APOLLO and the predicate device

	APOLLO	**Philips Omnidiagnost Eleva**
Intended use	Remote controlled radiology table, collimator and spot film device	Remote controlled radiology system inclusive of remote controlled table, collimator, spot film device, image intensifier system
Working height (table top center to floorplate)	600 –1400 mm	840 –1140 mm
Table tilt movement	-90° - +90°	-90° - +90°
Table tilt speed	4.5 –6.5°/sec	Variable 2-4.5°/sec
Table top suspension	Two sides suspension	Single side (left or right)
Table top material	2379x750 Plastic laminate or carbon fiber	2250 x 660 mm carbon fiber
Table top movement	Patient remain stationary during all scan movments	Patient remain stationary during all scan movments
Table top absorption	Plastic:< 0.5mm Al Carbon fiber: <0.3 mm Al @ 100kV, HVL 2.7mm Al	<= 1.1 mm Al eq.
Shape	Curved for max patient comfort and autocentering	Curved for max patient comfort and autocentering
Max patient weight	150 kg	200kg
Skin to film distance	65 mm	105 mm
Lateral scan distance	-160 - +160 mm	-160 - +160 mm
Lateral scan speed	30 mm/sec	Variable 10 – 50 mm/sec
Longitudinal scan distance	1600 mm	1550 mm
Longitudinal scan speed	30 – 200 mm/sec	Variable 20-120 mm/sec
Table column angulation	-40° - +40°	-40° - +40°
Table column angulation speed	11.2 °/sec	Variable 4°-8°/sec
Source image distance	Continuous variable between 1000 and 1500 mm	Continuous variable between 1100 and 1500 mm
Tube rotation	Manual +/-180° with stops at	Manual –90° -+180° with

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	0°:+/-40°;+/-50°;+/-90°; 180°	stops at 0°-40°-90°
Image intensifier lift	32 mm in 0.8 sec	32 mm in 0.8 sec
Collimator	Square/rectangular. Iris optional	Square/rectangular and Iris
Compressor movement	Motorized and parkable	Motorized and parkable
Compressor pressure	Adjustable between 30 and 150 N in steps of 5 N	Adjustable between 40 and 160 N
Automatic spot film device		
Cassette size	From 13x18cm to 35x43	From 20x20 to 35x43
Sudivisions	1, 2, 3, 4 in line 4, 6 in cross	1, 2, 3, 4 in line 4, 6 in cross
Load unload time	2 sec	2 sec
Preparation time for exposure	0.8 sec (min)	1.2 sec
Rapid sequence	yes	6 exposure in 4 sec
Grid	parkable	parkable
Tomography		
Movement	Arc- plan motion: at 45°, 30°, 20°, 7°	Linear at 40°, 20° or 8°
Layer height range	0 – 300 mm with automatic layer height increments	10 – 250 with automatic layer height increments
Sweep time	2 sec: 4 0 or 2.5 sec at 45° 2.7 or 1.3 sec at 30° 1.8 or 0.9 sec at 20° 0.6 0r 0.3 sec at 7°	2 speeds: 3 0 or 1.5 sec at 40° 1.5 or 0.75 sec at 20° 0.6 or 0.3 sec at 8°

Indication for use.

The indication for use of the APOLLO is: **radiology and fluoroscopy investigations** when installed in conjunction with adequate image intensifier, image acquisition systems, X-ray generators and X-ray tubes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2005

Villa Sistemi Medicali S.p.A.
% Ms. Veronica Meridith
Official Correspondent
Del Medical Imaging
11550 West King Street
FRANKLIN PARK IL 60131

Re: K050190
Trade/Device Name: APOLLO
Regulation Number: 21 CFR 892.1980
Regulation Name: Radiologic table
Regulation Number: 21 CFR 892.1670
Regulation Name: Spot-film device
Regulation Number: 21 CFR 892.1610
Regulation Name: Diagnostic x-ray beam-limiting device
Regulatory Class: II
Product Code: KXJ, IXL, and KPW
Dated: January 25, 2005
Received: February 10, 2005

Dear Ms. Meridith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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5.1. Indication for use Statement

510(k) Number:

Device Name: **APOLLO**

The indication for use of the APOLLO is: **radiology and fluoroscopy investigations** when installed in conjunction with adequate image intensifier, image acquisition systems, X-ray generators and X-ray tubes.

Prescription Use ✓

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050190