

OCT 31 1997

Apollo™ 510(k) Summary - Appendix 5

August 1997

K972882

510k Summary  
as required by 807.92(c) for  
Norland Apollo™ Bone Densitometer  
Prepared 4 August 1997

Submitted by: Norland Corporation  
W6340 Hackbarth Road  
Fort Atkinson, WI 53538  
Reg. # 2124648  
920-563-8456

Contact Person: Mr. Terry Schwalenberg  
Director Regulatory Affairs

Device Trade Name: Norland Apollo™ X-Ray Bone Densitometer

Common Name: Dual energy x-ray bone densitometer

Classification: Bone densitometer, (21 CFR 892.1170), product code 90KGI; Class II

Predicate Devices: OsteoAnalyzer bone densitometer (K891582)  
Dove Medical Systems, Newbury Park, CA

pDEXA bone densitometer (K931996)  
Norland Corporation, Fort Atkinson, WI

Description of Device: Apollo™ is a low cost, portable, easy-to-use bone densitometer which uses low dose x-ray technology to assess the bone density of the heel. Because Apollo™ uses the DXA technique, a water bath is not required.

Intended Use: The Apollo™ can be used whenever it is desirable to do a bone assessment of the heel. Bone assessments are of interest in many medical disciplines such as nephrology, endocrinology, rheumatology, gynecology, etc. The Apollo™ assesses the heel and provides BMC, Area, and BMD. It compares a scan to previous scans of the same subject and provides Long Term % Change and Short Term % change. It also provides user selectable modes which trade off scan speed for precision.

Substantial  
Equivalence to  
Predicate Devices: Apollo™ is similar to the pDEXA in that it uses the dual energy x-ray absorptiometry (DXA) technique and the proven pencil beam scan method. Apollo™ is similar to the OsteoAnalyzer in that it scans the same area of the heel as does the OsteoAnalyzer.

The Apollo™ is an improvement over the OsteoAnalyzer because its DXA technology inherently eliminates the water bath; and because it has reduced scan times. Apollo™ uses two detectors so that two radiometric scans are performed for each mechanical scan; thereby doubling the scan speed without complicating the mechanicals. The detectors are small enough and close enough to preserve the bone edge and area performance inherent in the pencil beam geometry; unlike the distortions seen with fan beam and cone beam geometries.

Apollo™ provides two scan modes, High Speed, and High Precision. The High Speed mode completes a scan in < 1 minute with a precision of 1.8 % coefficient of variation (CV). The High Precision mode takes < 3 minutes for a scan and delivers a precision of 1.2 % CV. These precision values were established via a clinical study involving 33 subjects with 6 scans each. Patient dose is about 1 mrem and scatter radiation is less than 0.1 mrem/hr.

## Comparison Table

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ITEM	APOLLO™	OSTEOANALYZER	pDEXA
Scan Site	Os calcis (heel)	same	Forearm
Scan Method	DXA Pencil beam Rectilinear scanning	SXA same same	DXA same same
Indications for Use	Heel bone assessment	same	Forearm assessment
Intended Uses	Provides BMC, Area, BMD, % Long term change, & % Short term change	same	same
Operating Modes	Hi Speed Hi Precision	Standard Hi Speed	Standard High Speed High Precision
Scan Time	< 1 minute (High Speed) < 3 minutes (High Precision)	3.5 min. (Standard) 2.0 min. (Hi Speed)	< 2 min. (High Speed) 5 min. (High Precision)
Precision	1.8 % (High Speed) 1.2 % (High Precision)	< 1 %	1.8 % (High Speed) 1.4 % (High Precision)
Accuracy	2 % to hydroxapatite	dipotassium hydrogen phosphate	hydroxapatite
Machine-to-machine variance	2 % for BMD	not specified	2% for BMD
Dose	< 1 mrem	1.3 mrem	< 4.5 mrem
Technology	DXA (no water)	SXA (water needed)	DXA (no water)
Detectors	two CdZnTe (or CdTe)	one CdTe	two CdZnTe (or CdTe)
Tube Voltage	60 kVdc (constant)	36 kVdc (constant)	60 kVdc (constant)
Tube Current	0.10 - 0.20 mA	0.1 mA	0.12 mA
Filtration	>1.5 mm Al equivalent	same	same



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 31 1997

Terry Schwalenberg  
Director, Regulatory Affairs  
Norland Corporation  
W6340 Hackbarth Rd.  
Fort Atkinson, WI 53538-8999

Re: K972882  
Norland Apollo Bone Densitometer  
Dated: August 4, 1997  
Received: August 5, 1997  
Regulatory class: II  
21 CFR 892.1170/Procode: 90 KGI

Dear Mr. Schwalenberg:

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 requirement, 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/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): \_\_\_\_\_

Device Name: Norland Apollo X-Ray Bone Densitometer

Indications For Use:

The Apollo can be used whenever it is desirable to do a bone assessment of the heel. Bone assessments are of interest in many medical disciplines such as nephrology, endocrinology, rheumatology, gynecology, etc. The Apollo assesses the heel and provides BMC, Area, and BMD. It compares a scan to previous scans of the same subject and provides Long Term % Change and Short Term % change. It also provides user selectable modes which trade off scan speed for precision.

(printed on FDA Optional Format 1-2-96)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David L. Segura  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K972882

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)