K021527

Date: 8 May 2002

JUN - 7 2002

Sectra Document Number: 3-02.832-1.0

510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92c)

Date Prepared:

May 8 2002

Submitter's Information:

Sectra Imtec AB
Teknikringen 2
SE-583 30 Linköping
Sweden
Phone: +1 46 13 23 52 00
Fax: +1 46 13 21 21 85

Trade Name, Common Name, Classification:

Trade name:	Sectra Osteoporosis Package
Common Names:	Bone Densitometer
Classification Name:	Bone Densitometer (90 KGI) (21 C.F.R. § 892.1170)

Predicate Device:

Applicant:	Pronosco A/S
510(k) Number:	K002500
Device:	X-Posure System Version 2 RAD

Device Description:

The Sectra Osteoporosis Package is intended for use to estimate bone mineral density (BMD) in the forearm and to assess increased risk of osteoporotic fracture according to World Health Organization (WHO) criteria.

Sectra Osteoporosis Package features:

- indirect "DICOM capability" via the Sectra IDS5 Radiology workstation, i.e. it uses digital image data according to the DICOM standard.
- single screen user interface reached via a right click on an image in a Sectra IDS5 Radiology Workstation.
- operates in two modes: Clinical mode and Research mode.

Indications for Use:

The device is intended for use to estimate bone mineral density ("BMD") in the forearm and to assess increased risk of osteoporotic fracture according to World Health Organization ("WHO") criteria. The device is indicated specifically for use to: (1) assist the physician in diagnosing subjects who already have been identified to be at risk for suffering from osteoporosis, together with other known risk factors (e.g., prior history of fractures, advanced age, low body weight, lack of physical exercise, lack of exposure to sunlight, insufficient dietary intake of vitamin D and/or calcium, and smoking); and (2) compare the BMD estimate with a reference population comprised of young normals and age-matched normals to compute T-scores and Z-scores, respectively.

Technological Characteristics:

The Sectra Osteoporosis Package will run on the Windows NT 4.0 and Windows 2000 operating systems for PCs (as a minimum and depending upon system configuration).

Performance Data:

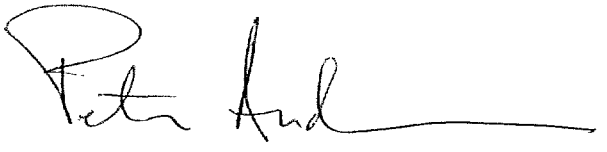
The subject device is developed according to ISO 9001:2000 and complies with ACR/NEMA Digital Imaging Communications in Medicine version 3.0.

Conclusion:

The Sectra Osteoporosis Package is substantially equivalent to the previously cleared X-Posure System Version 2 RAD (K002500). The intended use and indications for use are identical. The principal difference in technological features from the predicate devices is the image source. That is, the Sectra Osteoporosis Package analyzes computed radiography ("CR") images obtained directly in digital format. This is in contrast to the predicate devise, which is limited to analyzing either conventional X-ray images alone that must first be separately digitized by using a scanner. This difference in technical characteristics between the subject device and the predicate device does not raise any new questions of safety or effectiveness, because the question of whether the images are of sufficient quality to permit BMD analysis is common to both devices. Also, both devices use essentially the same DXR techniques to analyze the given images. Both in vitro and in vivo performance testing has been conducted to verify that this design difference does not impact either safety or efficacy.

Additionally, the Sectra Osteoporosis Package can receive digital DICOM images that have been stored in a third party's network or PACS system, while the predicate device did not have this option. However, the additional ability to retrieve digital images stored on these other information systems has been validated by the company and in no way affects how the software analyzes BMD or the quality of this analysis.

The other difference is that the Sectra Osteoporosis Package is integrated with a Sectra IDS5 Radiology Workstation giving the operator direct access to the BMD analysis. However, essentially the Sectra Osteoporosis Package is the same as the predicate device, its stand-alone counterpart, and presents no new safety or effectiveness concerns (as discussed above). Furthermore, as validated by the company, the packaging of these systems together in no way impacts the device's safety and effectiveness. Therefore, the Sectra Osteoporosis Package and the predicate device are substantially equivalent.



Peter Andersson
Regulatory Affairs Officer
Sectra Imtec AB
Teknikringen 2
SE-58330 Linköping
Sweden

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2002

Sectra Imtec AB
% Mr. Carl Alletto
OTech, Inc.
1100 Lakeview Blvd.
DENTON TX 76208

Re: K021527
Trade/Device Name: Sectra Osteoporosis Package
Bone Densitometer
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone Densitometer
Regulatory Class: II
Product Code: 90 KGI
Dated: May 8, 2002
Received: May 10, 2002

Dear Mr. Alletto:

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 (PMA), it may be subject to 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

K021527

510(k) Number:

Device Name: Sectra Osteoporosis Package

Indications for Use:

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(1) assist the physician in diagnosing subjects who already have been identified to be at risk for suffering from osteoporosis, together with other known risk factors (e.g., prior history of fractures, advanced age, low body weight, lack of physical exercise, lack of exposure to sunlight, insufficient dietary intake of vitamin D and/or calcium, and smoking); and
(2) compare the BMD estimate with a reference population comprised of young normals and age-matched normals to compute T-scores and Z-scores, respectively.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over -The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David C. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021527