K032157

SEP 2 4 2003

510(k) SUMMARY

Company Identification:

Telemis S.A.
Avenue du Grand Cortil, 34
B-1348 Louvain-la-Neuve
Belgium
Phone: +32-10-48 00 11 Fax: +32-10-48 00 20

Official Correspondent:

Eric Thibau, European Certification Partners, Inc.
7560 Lindbergh Drive
Gaithersburg, MD 20879
Tel: (240) 631-8558 FAX: (240) 631-8228

Date Summary Prepared: September 1, 2002

Name of the Device:

Trade Name:	*Telemis-Medical*
Common name:	PACS
Classification name:	Picture Archiving and Communication System

Predicate Device:

Name of the device:	iSite Radiology
510(K) Number:	K013630
Company:	Stentor, Inc. 385 Oyster Point Blvd., Suite 8B Establishment Registration #2954704 Tel: (650) 866-4100 Fax: (650) 866-4197

Device Description:

The *Telemis-Medical* Solution is a Medical Image Management software package designed to perform required functions for the import, storage, archive, distribution, review, analysis of digital medical images in DICOM 3.0 and other formats. The Telemis Medical Solution consists of the *TM-AutoAcquisition, TM-Worklist, TM-Server, TM-Reception, TM-ReceptionHE, TM-Reception Lite, TM-Home, TM-Link and TM-Publisher.*

TM-AutoAcquisition acquires image studies from medical devices, converts them into secure multimedia documents and sends them to the *TM-Server.* The *TM-Worklist* is used by the *TM-AutoAcquisition* to validate patient information. The TM-Server manages documents and security permissions. The TM-Reception allows

authenticated users to retrieve, manage, review and process their image documents. The *TM-ReceptionHE* is an enhanced *TM-Reception* that provides users with extra image processing features. The *TM-Reception Lite* allows users to manage and review local image documents. The *TM-Home* delivers *TM-Reception*'s features for personal use. The *TM-Link* provides transparent integration between Telemis-Medical and Electronic Patient Record system. The *TM-Publisher* makes image study summary available on CD-ROM, paper or e-mail.

Intended Use:

The Telemis-Medical solution is a software package intended for the acquisition, management, distribution and display of medical images within the healthcare system. It can be marketed as software only, as well as packaged with standard PC hardware. It was developed with the Java® technology that allows the software to run on every operating system implementing a Java Virtual Machine Environment (f.i. Windows, MacOS, Unix). It communications using the standard TCP/IP network protocol.

Technological comparison to Predicate Device:

The Telemis-Medical solution is substantially equivalent to the Stentor, Inc. iSite Radiology (K013630) system, in that it receives DICOM images, converts them to lossless or lossy (wavelet or jpeg) format, store, transmit and displays them. The intended use and technological characteristics of the Telemis-Medical solution are virtually identical to the Stentor iSite system. Any differences between the *Telemis-Medical* solution and the equivalent devices have no significant influence on safety or effectiveness.

Conclusion:

It is our conclusion that there is no software component in the *Telemis-Medical* solution or hardware component that would be used in conjunction with the *Telemis-Medical* solution that we know of, whose failure or latent design flaw would be expected to result in death or injury to a patient. Thus, the "Level of Concern" of the Telemis Medical Solution product is "minor".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2003

Mr. Thomas J. Bouchard
Official Correspondent
Telemis-Medical S.A.
7560 Lindberg Drive
GAITHERSBURG MD 20879

Re: K032157
Trade/Device Name: Telemis-Medical Solution
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: May 20, 2003
Received: July 14, 2003

Dear Mr. Bouchard:

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 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 the 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" (21CFR Part 807.97) you may obtain. 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

K032157

510(k) Number (if known):

Device Name: *Telemis-Medical*

Indications For Use:

The *Telemis-Medical* solution is a software package intended for the acquisition, management, distribution and display of medical images within the healthcare system.
It can be marketed as software only, as well as packaged with standard PC hardware. It was developed with the Java® technology that allows the software to run on every operating system implementing a Java Virtual Machine Environment (f.i. Windows, MacOS, Unix). It communications using the standard TCP/IP network protocol.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032157