K070796

3 510(k) Summary

APR - 6 2007

3.1 Owner Information

Owner´s Name:	CHILI GmbH
Owner´s Address:	Burgstrasse 61 D-69121 Heidelberg, Germany Phone: (+49) 6221 1 80 79 - 10 Fax: (+49) 6221 1 80 79 - 11
Representative:	Peter Kayser (CEO) Burgstrasse 61 D-69121 Heidelberg, Germany Phone: +49 6221 180 79 10 Fax: +49 6221 180 79 11
Date prepared:	March 12, 2007

3.2 Device name

Trade Name:	will be first marketed as CHILI PACS Version 2006-09
Common Name:	PACS
Classification Name:	Picture Archiving and Communication System
Classification Number:	**Class II**
Classification Code:	21 CFR §892.2050
Classification Panel:	Radiology
Predicate Device:	syngo Imaging Version V20A (K052461)
Reason for the 510 (k):	New device

3.3 Device Description and Intended Use

This premarket notification covers CHILI's PACS system "CHILI PACS".

CHILI PACS is a „software only"- solution. It is a modular system, consisting of modules which can be combined for the specific needs of a customer, including a backend communication and storage component and different workplace deployments for medical imaging tasks and applications.

CHILI PACS is the integrated radiology suite for radiological practices and community hospitals. Important factors are the centralized server structure, the wide-ranging data distribution and the overall integrated concept, ranging from reporting and archiving as well as image and report distribution.

CHILI PACS Integrated Workplaces / CHILI PACS Image Distribution.

The three CHILI PACS workplace deployments

a) *CHILI Web* - for image distribution (web-based viewing application - suited for primary diagnosis)

b) *CHILI Workstation* - for reporting, inside as well as outside of the radiology (standalone workstation or client workstation connected to server)

c) *CHILI 3D-PlugIn (optional)* - for 3D- and 4D reconstructions of image slices generated by digital modalities and stored in the DICOM format (not intended for primary diagnosis)

are medical diagnostic and viewing workstations intended for manipulating, reading, reporting, viewing and communicating / distributing of radiological softcopy images and so allows radiologists, radiological technicians and health care professionals to receive and process all data needed.

Data Management: CHILI Server.

Ensures all authorized personnel fast and continuous access to radiological data. It's main functionality ranges from availability of images having regard to data security, open interfaces, storage media, central system administration, back-up, software distribution to providing a flexible storage hierarchy.

The main purpose is storing and archiving of radiological softcopy images and structured (DICOM) reports.

Integration: CHILI Workflow Integration.

The Workflow Management enables by integration of any HL7- / DICOM-compatible HIS, RIS (IHE Year 5) and other information systems to the CHILI PACS a consistent workflow - from patient registration to requirement scheduling to a personal worklist and supports therefore reporting, documentation or administrative tasks.

3.4 Device Technological Characteristics

CHILI PACS is a "software only"-system, which will be delivered on CD-ROM / DVD and installed by service engineers. Hardware requirements to be met are therefore defined.

The backend communication and storage solution is based on the SuSE Linux operating system. The workplaces are based on Windows XP or SuSE Linux operating system, or MacOS X in case of CHILI Web.

The herewith described CHILI PACS supports DICOM formatted images and objects.

3.5 Testing and Equivalence

The CHILI PACS, addressed in this premarket notification, is substantially equivalent to the following commercially available device:

- syngo Imaging Version V20A K052461

The CHILI PACS described in this 510(k) has the same intended use and similar technical characteristics as the devices listed above.

In summary, CHILI is of the opinion that CHILI PACS does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate devices.

3.6 General Safety and Effectiveness Concerns

The device labelling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, CHILI GmbH adheres to recognized and established industry practice and standards.

3.7 Guidance Documents

- Guidance for the Submission of Premarket Notification for Medical Image Management Devices, July 27, 2000.
- Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices, May 11, 2005.
- Off-The-Shelf Software Use in Medical Devices, September 9, 1999

Third Party Review Quality Assessment

Section 1 – Submission Information

510(k) No.: K070796___ Third Party Organization: TÜV SÜD America.

Third Party's Primary Reviewer(s): Stefan Preiss

ODE/OIVD Division: DRARD Branch/Team: Radiological Devices Branch

Section 2 – 510(k) Decision

Third party recommendation: SE √___ NSE ____ Other (specify): _____

ODE/OIVD final decision: SE _√___ NSE ____ Other (specify): _____

Section 3 – Assessment of Third Party Review

Review Element	Rating (check one)		
	Adequate	Minor Issue(s)	Major Issue(s)
a. Determination of device eligibility for third party review	√		
b. Extent of pre-submission consultation with ODE/OIVD division			
c. Organization and format of review documentation	√		
d. Determination of 510(k) administrative completeness (screening review)	√		
e. Summary of device characteristics, intended use, and performance (including accessories, if applicable) and reason for 510(k) submission	√		
f. Comparison to legally marketed devices—identification and analysis of key similarities and differences	√		
g. Rationale for conclusions and recommendation	√		
h. Use of guidance documents and standards	√		
i. Resolution of 510(k) deficiencies and FDA requests for additional information			
j. Scope of reviewer expertise and use of consulting reviewers			
k. Other (specify):			

Comments (explanation of ratings/issues): _____

Section 4 – ODE/OIVD Assessor Information

Assessed by: Sunder Rajan Date: April 5, 2007 Tel. No.: 240 276 3968

Routing: Division--Clip completed assessment (this page only) to inside front cover of 510(k).
DMC--Forward this page only to Eric Rechen, POS/ODE, Rm. 120J, Corp. Blvd. (HFZ-402).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Chili GmbH
c/o Mr. Stefan Preiss
Responsible Third Party Official
TÜV SÜD America, Inc.
1775 Old Hwy 8 NW, Ste. 104
NEW BRIGHTON MN 55112-1891

APR - 6 2007

Re: K070796
Trade/Device Name: CHILI PACS
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 21, 2007
Received: March 23, 2007

Dear Mr. Preiss:

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

2 Indications for Use

510(k) Number (if known): _____

Device Name: CHILI PACS

Indications For Use:

The CHILI PACS is a Picture Archiving and Communication System (PACS) intended to enhance the complete imaging workflow, i.e.

- Displaying
- Processing
- Reading
- Reporting
- Communicating / distributing
- Storing / archiving of radiological softcopy images and
- Storing / archiving of structured (DICOM) reports.

The system is a "software only" solution and is intended to assist the physician in diagnosis or treatment planning (excluding screening and primary diagnosis of mammography images).

Therefore CHILI PACS supports the following generic imaging workflow:

- Receive scheduled exams from IS at the CHILI PACS archiving component CHILI Server
- Provide relevant prior exams and reports (Structured Reports only) to the Modalities and Workplaces
- Receive and store new exams from the Modalities at the CHILI Server
- Prepare images for reading
- Report new images, if required by comparing them with prior exams and reports
- Demonstrate exams at Radiological Demos
- View exams and reports at Workplaces outside Radiology (e.g. Surgery, Intensive Case Unit, wards, external referring physicians).

Note: The workstation deployment CHILI 3D-PlugIn is not intended for primary diagnosis.

Prescription Use __X___ ~~AND~~/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) 21 CFR 801 Subpart C)

(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, and Radiological Devices
510(k) Number K070796