K02 3467

JAN 0 7 2003

EXHIBIT #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

1. Submitter's Identification:

Softlink International Inc.
199 Main Street
Suite 314
White Plains, NY 10601

Contact: Mr. Praveen Lobo
Softlink International
Tel: 914-582-1047
Fax: 914-686-4666

Date Summary Prepared: October 14, 2002

October 8, 2002

2. Name of the Device:

HCP DICOM Net®

3. Predicate Device Information:

1. Digital Imaging Systems, K#954159, Camtronics, Ltd., Hartland, WI (892.2050, Product Code LLZ).

2. The TCS-Telecardiology System, Medcon Ltd., Efrat, Israel (892.1600, Product Code IZI).

3. WriteStar and ViewStar, K#964274, ComView Corp., Montrose, Ny (892.2010, Product Code LMB).

4. Device Description:

HCP DICOM Net® is a computerized system that acquires images which are captured by cardiac catherterization laboratories and other modalities like Echocardiograms, MRI & CT. These images are acquired through a video source or a DICOM3 interface of the

modality. These images are then stored in DICOM3 format on Hard Disk Drives, Magnetic Tape, CD-R or DVD. If images are acquired through a video source, in a non-DICOM3 format then these images are converted into a DICOM3 format before they are stored. After storage these images are retrieved and displayed on workstations for convenient review and analysis. Analysis of images is provided via approved industry standard third party software. These workstations are also capable of reading DICOM3 images from CD and DVD media and uploading them to the image store for retrieval, viewing and analysis at a later time.

5. Intended Use:

HCP DICOM Net® is a software device intended to acquire and store medical images studies from catherterization laboratories, Echo cardiograms, CT & MRI and other such modalities. In addition, HCP its DICOM Net provides image enhancement and filtering tools for viewing of selected images. It also imports image studies from DICOM CD's/DVD's, makes copies of image studies and converts and exports image studies into DICOM3 and other commercial file formats. HCP DICOM Net® also integrates industry standard third party approved software within its application to allow for analysis of the acquired image.

6. Comparison to Predicate Devices:

HCP DICOM Net® provides convenient acquisition, storage and review of DICOM3 images like the ComView WriteStar and Medcon TCS-Cardiology System. HCP DICOM Net® unlike the Camtronics Digital Imaging System and ComView ViewStar and WriteStar, is a software only device that runs on industry standard PCs running windows based operating systems. HCP DICOM Net®, like the Camtronics Digital Imaging System and the ComView ViewStar/WriteStar System, can acquire analog images and convert them to a digital DICOM 3 image format and this functionality is intended to replace film.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the HCP DICOM Net® device in the intended environment of use is supported by testing that was conducted in accordance with EN-1441 (Risk Analysis) and software validation and verifications testing. In addition, a DICOM Conformance Statement was provided with this submission to DICOM Voluntary Standards.

8. Discussion of Clinical Tests Performed:

Not applicable

9. Conclusions:

The HCP DICOM Net® device has similar intended uses and similar characteristics as the predicate devices. Moreover, software testing contained in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the HCP DICOM Net® device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 7 2003

SoftLink International, Inc.
% Ms. Susan D. Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd.
Suite 200
GREAT NECK NY 11021

Re: K023467
Trade/Device Name: HPC DICOM Net
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: October 14, 2002
Received: October 16, 2002

Dear Ms. Goldstein-Falk

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.

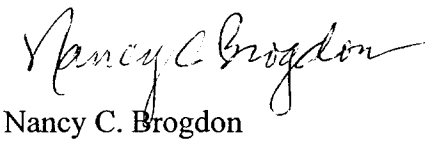
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K02 3467

Device Name Softlink International Inc. HCP DICOM Net®

Indications For Use:

HCP DICOM Net® is a software device intended to acquire and store medical images studies from catheterization laboratories, Echo cardiograms, CT & MRI and other such modalities. In addition, HCP DICOM Net® provides image enhancement and filtering tools for viewing of selected images. It also imports image studies from DICOM CD's/DVD's, makes copies of image studies and converts and exports image studies into DICOM3 and other commercial file formats. HCP DICOM Net® also integrates industry standard third party approved software within its application to allow for analysis of the acquired image.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seyonne

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023467

Prescription Use ✓