K132183
Page 1 of 3

510(k) Summary of Safety and Effectiveness (in accordance to 21CFR 807.92)

Submitter details

Bar-Code Computers Ltd.
2 Hayozma St, Tirat Hacarmel 39120, Israel Telephone +972-4-8509569

Submission Contact: Dan Laor 6 Sireni St., Haifa, 32972, Israel.
Preparation Date: 16th September 2013

Details of the submitted Device

Proprietary Name:	DICOM Video
Regulation Description:	Medical image digitizer.
Regulation Number	892.2030
Product Code:	LMA
Committee/Panel:	Radiology
Device Class:	2

OCT 0 3 2013

Reason for 510(k) Submission:

New Device

Identification of the Legally Marketed Predicate Device

K000411 CHILI VIDEO/VIDEO PRO

Device Description

The DICOM Video is a software package, which is installed in an Off - The - Shelf Host PC. The device is interfaced and configured to a hospital Local Area Network (LAN).
The DICOM Video receives patients' list from the Hospital Modality Work List (MWL) server and digital files input data (in text, images or video formats). The device records the received data, stores it, transfers the studies into standard DICOM files, and transmits the DICOM files via the LAN to the Hospital PACS.

The DICOM Video can be interfaced to a Host Acquisition Device in order to receive analog video signals. The data is digitized, stored, optionally edited, transferred into standard DICOM files, and transmitted as DICOM files via the LAN to the Hospital PACS.

The device can also retrieve DICOM studies from the PACS and display them on the user screen.

Intended use and indications for Use

The DICOM Video software package is intended for use by authorized personnel to acquire individual or sequences of images and to allow the user to input patient demographics related to the image. The device transforms imaging studies to DICOM format before they are made available to other locations in the network. The DICOM Video is indicated to receive studies in various digital formats (text, still images and video) or digitized video signals from acquisition host devices. The device operations include capturing the data, recording, storing, editing and transferring it to the clinic PACS as DICOM files.

Comparison with the predicate device

Intended Use & Indications For Use: Similar to the predicate device, the DICOM Video is intended for use by authorized personnel to acquire individual or sequences of images. Both devices allow the user to input patient demographics. In addition the DICOM Video transforms

imaging studies to DICOM format before they are made available to other locations in the network.
Similar to the predicate device, the DICOM Video is indicated to receive studies in various formats. The devices' operations include capturing the data, recording, storing and editing. In addition the DICOM Video is communicating DICOM files with the hospital PACS .

Characteristics Comparison

Category	**Predicate Device** K000411 . CHILI VIDEO/VIDEO PRO	**Subject Device** DICOM Video
Used to grab images from modalities that do not have digital export functions	Yes	Yes
Data Capture: Can grab single images	Yes	Yes
Data Capture: Can grab sequence images	Yes	yes
Viewing	Yes	Yes
Editing	Yes	Yes
Storing	Yes	Yes
Grabbed image can be manipulated.	No	No
Images can be added to a study	Yes	No
user enters patient demographic data	Yes	Yes
Images can be stored with demographic data	Yes	yes
Data Source	Includes: Still images & Video	Includes: Files of Text, Still images & Video
Control s	Software package included	Software package included
Supporting Hardwar PC	Included	Company specified PC
Frame grabber	Various boards available	Company specified board
Can be used with any device that has a video data stream output	Yes	S Video & Composite formats, ONLY
User selectable video sources	Yes	Pre-selected single video source, only
Communication	Not provided	TCP/IP Ethernet using DICOM 3.0 protocol

Design Verification and Validation

The device has been designed, verified and validated complying to 21CFR 820.30 regulations. The device was tested in conformance to the requirements of NEMA PS 3.1 - 3.20 (2011) DICOM (Digital Imaging and Communications in Medicine) set and was found conforming.

Performance data

Bench data:

The device performance has been verified by testing the software with respect to predefined software test plan.

The device has been validated by testing the performance with respect to predefined test plan in end - user environment.

Methods of testing the device safety & effectiveness adhere to state-of-art standards. The tests results demonstrated that the device output meet the design input and support the indications for use.

Clinical Data:

Clinical data is not included.

Substantial Equivalence

The above presented data demonstrate that:

a. The predicate device K000411 CHILI VIDEO/VIDEO PRO is legally marketed.
b. The submitted device and the predicate device have the same intended use.
c. The technological characteristics are equivalent and do not raise different questions of safety and effectiveness.

Conclusion: Based on the data above, it is Bar Code Computers' opinion that the submitted device and the predicate device are substantial equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

Bar-Code Computers Ltd.
% Mr. Dan Laor
Q&R Consultant
6 Sireni
Haifa 32972
ISRAEL

Re: K132183
Trade/Device Name: DICOM Video
Regulation Number: 21 CFR 892.2030
Regulation Name: Medical Image Digitizer
Regulatory Class: II
Product Code: LMA
Dated: July 8, 2013
Received: July 19, 2013

Dear Mr. Laor:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

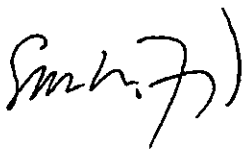
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132183

Device Name: DICOM Video

Indications for Use:

The DICOM Video software package is intended for use by authorized personnel to acquire individual or sequences of images and to allow the user to input patient demographics related to the image. The device transforms imaging studies to DICOM format before they are made available to other locations in the network. The DICOM Video is indicated to receive studies in various digital formats (text, still images and video) or digitized video signals from acquisition host devices. The device operations include capturing the data, recording, storing, editing and transferring it to the clinic PACS as DICOM files.

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 *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K132183