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

HEPATIQ LLC
% Mr. Dipu Ghosh
CEO
1150 Main Street, Suite E
IRVINE CA 92614

December 17, 2014

Re: K142891
Trade/Device Name: HEPATIQ
Regulation Number: 21CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 27, 2014
Received: Oct. 3, 2014

Dear Mr. Ghosh:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Robert A. Ochs, PhD
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142891

Device Name
HEPATIQ

Indications for Use *(Describe)*
HEPATIQ is a nuclear medicine software application used to display and process liver-spleen images.
The results obtained may be used as a tool, by a nuclear physician, in quantifying liver-spleen images.
The data processed may be derived from any nuclear medicine liver-spleen procedure.
The HEPATIQ software should only be used by qualified nuclear medicine professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5 510(K) SUMMARY K142891

In accordance with 21 CFR 807.92, the following summary of the information in the 510(k) submission is provided.

5.1 807.92(A)(1)

Summary Date:	9/27/2014
Submitter:	HEPATIQ LLC 1150 Main Street, Suite E Irvine, California 92614 USA.
Primary Contact:	Dipu Ghosh, MSEE, MBA. Chief Executive Officer Phone: (949) 250-1065 ext. 124 Fax: (949) 250-1075 E-mail: dghosh@hepatiq.com
Secondary Contact:	John Hoefs, MD. Chief Operating Officer Phone: (714) 883-2208 Fax: (949) 250-1075 E-mail: jhoefs@hepatiq.com

5.2 807.92(A)(2)

Trade Name:	HEPATIQ
Common Name:	Radiology Image Processing Software
Device:	System, Image Processing, Radiological
Regulation Number:	21 CFR 892.2050
Regulation Description:	Picture Archiving & Communication System (PACS)
Review Panel:	Radiology
Device Class:	Class II
Product Code:	LLZ

Indication For Use:	HEPATIQ is a nuclear medicine software application used to display and process liver-spleen images. The results obtained may be used as a tool, by a nuclear physician, in quantifying liver-spleen images. The data processed may be derived from any nuclear medicine liver-spleen procedure. The HEPATIQ software should only be used by qualified nuclear medicine professionals.

5.3 807.92(A)(3) – PREDICATE DEVICE

Predicate Device:	PEGASYS Ultra
Manufacturer:	ADAC Laboratories
510(k) Number:	**K993946**
Product Code:	**LLZ**
Regulation Number:	21 CFR 892.2050
Regulation Description:	Picture Archiving & Communication System (PACS)

5.4 807.92(A)(4) – DEVICE DESCRIPTION

Device Description:	HEPATIQ is Microsoft Windows software that allows the user to display and process nuclear medicine liver-spleen images. HEPATIQ software runs on any nuclear medicine workstation running Windows XP SP3 or later. HEPATIQ software provides the user a means for quantification of nuclear medicine liver-spleen images.

5.5 807.92(A)(5) – INTENDED USE

Intended Use:	HEPATIQ is a nuclear medicine software application used to display and process liver-spleen images. The results obtained may be used as a tool, by a nuclear physician, in quantifying liver-spleen images. The data processed may be derived from any nuclear medicine liver-spleen procedure. The HEPATIQ software should only be used by qualified nuclear medicine professionals.

5.6 807.92(A)(6) – TECHNOLOGICAL CHARACTERISTICS

HEPATIQ software has two major technologies:

Image Display: HEPATIQ interfaces with the hospital PACS to display nuclear medicine liver-spleen images using the standard Digital Imaging and Communications in Medicine (DICOM) protocols..

Image Quantification: Regions of interest (ROI) are identified automatically for the liver and spleen. An ROI is also automatically identified for the marrow between the liver and the spleen. The user is required to review and approve these ROI or re-draw them manually. ROI parameters are computed. Image quantification parameter Perfused Hepatic Mass (PHM) is calculated from the ROI parameters using standard formulas. A report is prepared showing serial PHM values and saved on PACS.

5.6.1 Technological Similarities

The following table summarizes the similarities in the technological characteristics of HEPATIQ and the predicate device PEGASYS.

Technology	**PEGASYS (Predicate)**	**HEPATIQ**	**Comparison**
Computer	General purpose commercial computer (Sun)	General purpose commercial computer (Intel)	Both products run on general purpose commercial computers. Neither product is relying on a specialized computer.

Technology	PEGASYS (Predicate)	HEPATIQ	Comparison
Operating System	General purpose commercial operating system (UNIX)	General purpose commercial operating system (Windows)	Both products use a general purpose commercial operating system. Neither product is relying on a specialized operating system. Both UNIX and Windows provide standard operating system functions for the display and processing of images.
Launch	PEGASYS Image Manipulation application launched by clicking on an icon.	HEPATIQ application launched by clicking on an icon.	Both products use a graphical user interface icon to launch the application.
PACS Interface	DICOM	DICOM	Both products use DICOM protocols to interface to the hospital PACS for downloading images and uploading reports.
Configuration	PEGASYS screens to set network and operational parameters.	HEPATIQ screens to set network and operational parameters.	Both products use a graphical user interface dialog screen to set configuration parameters.
Manual image processing	General purpose software tools for manual image processing.	General purpose software tools for manual image processing.	Both products provide similar manual software tools for: •Image Display •Frame Selection •Spleen Length •Summarized Transaxial Image •ROI Identification •ROI Calculations
User	Qualified nuclear medicine professionals	Qualified nuclear medicine professionals	Both products require users to be qualified nuclear medicine professionals.

5.6.2 Technological Differences

The following table summarizes the differences in the technological characteristics of HEPATIQ and the predicate device PEGASYS.

Technology	PEGASYS (Predicate)	HEPATIQ	Comparison
Automated image processing	No automation (manual calculation of PHM only)	Automated calculation of PHM	The only difference in the image processing by PEGASYS and HEPATIQ is the automation feature. Both produce results that are highly correlated with each other. Automation of the image processing is a feature of HEPATIQ that saves the user a tremendous amount of time. For validation of the automation feature, the PHM calculation was performed manually using PEGASYS and automatically using HEPATIQ for a set of test images. The PHM value obtained from the two devices were compared and found to be highly correlated thus validating the automation feature.

As the HEPATIQ and predicate device PEGASYS calculation of PHM are highly correlated, **the automation feature of HEPATIQ does not raise any different questions of safety or efficacy**.

5.7 807.92(B)(1) – NON-CLINICAL PERFORMANCE DATA

5.7.1 Design Controls

HEPATIQ was developed under the Quality System Regulation using Design Controls 21 CFR 820.30. This included establishing and maintaining procedures to ensure design requirements are met. All elements of the process have been documented, including design and development plan, design input, design output, design review, design verification, design validation, design transfer, design changes, and design history file.

5.7.2 Software Verification

HEPATIQ has successfully undergone extensive verification testing to ensure that all requirements for the software have been met.

A Software Verification Protocol was developed and executed. All verification tests passed and this was documented in a Software Verification Report. These results provide objective evidence that the outputs of the software design activity meet all of the specified requirements for that activity. For details on the verification testing performed, please see ***Section 12.9 - Verification Testing.***

5.7.3 Software Validation

Substantial equivalence was established by conducting a (non-clinical) validation test that collected performance data on HEPATIQ and the predicate device PEGASYS. The validation test consisted of directly comparing the manual processing of the liver-spleen images using the PEGASYS predicate device with the automatic processing of the same images using HEPATIQ.

A correlation analysis was performed between the manual PHM calculations using PEGASYS and the automatic PHM calculations using HEPATIQ. The analysis produced a coefficient of determination R2 of 97% which exceeded the validation criterion of a minimum R2 of 90%. Thus the validation test produced performance data that proved that HEPATIQ was substantially equivalent to PEGASYS.

As the HEPATIQ and predicate device PEGASYS calculation of PHM are highly correlated, the automation feature of HEPATIQ does not raise any different questions of safety or efficacy. For details on the validation testing performed, please see ***Section 12.10 - Validation Testing (Performance Data).***

5.7.4 Site Testing

Site testing was performed at a beta test hospital to test the installation procedures. The site testing was successful.

For details on the site test protocol, please see ***Attachment 11: H-026 – Site Test Protocol***.

For details on the site test results, please see ***Attachment 12: H-027 – Site Test Report***.

5.8 807.92(B)(2) – CLINICAL PERFORMANCE DATA

Based on the criteria listed under Section F of the guidance document: "***The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications***", no clinical testing of HEPATIQ was required or performed. For a detailed rationale, please see ***Section 20: Performance Testing - Clinical***.

5.9 807.92(B)(3) – CONCLUSION

Substantial equivalence of HEPATIQ and PEGASYS has been positively established in accordance with the flowchart in Appendix A of the guidance document: "***The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications***".

Decision	Question	Answer
1	Is the predicate device legally marketed?	**Yes** - PEGASYS is a legally marketed device
2	Do the devices have the same intended use?	**Yes** - HEPATIQ has the same intended use as PEGASYS.
3	Do the devices have the same technological characteristics?	**No** – There is one difference:- PEGASYS processes liver-spleen images manually while HEPATIQ processes them automatically (with manual overrides available to the user).
4	Do the different technological characteristics of the devices raise different questions of safety and effectiveness?	**No** – The automation feature of HEPATIQ does not raise different questions of safety and effectiveness. Validation testing proved that the PEGASYS manual processing and HEPATIQ automated processing are highly correlated.
5a	Are the methods acceptable?	**Yes** – Direct comparison of the processing of the same images on both PEGASYS and HEPATIQ was performed and standard statistical analysis used for comparison.
5b	Do the data demonstrate substantial equivalence?	**Yes** – Manual processing with PEGASYS and automatic processing with HEPATIQ were correlated with an R^2 of 97%, exceeding the validation requirement of a minimum of 90%.

Furthermore, no applicable mandatory performance standards or special controls exist for HEPATIQ. The product design, development and manufacturing conform to Quality System Regulations. Results of testing and standards conformance demonstrate safety and effectiveness of HEPATIQ.

We conclude that HEPATIQ and PEGASYS are substantially equivalent.