

510(k) Premarket Notification	ISSA™ Imaging and PHAROS
Summary of Safety and Effectiveness Information	Communication Products

1. Device Name:

Trade Name: *ISSA PHAROS*
 Common Name: Image communication and storage system
 Classification Name: System, Digital Image Communication Teleradiology System

2. Establishment Name & Registration Number:

Name: **VAMS TEC, D.O.O.**
 Number: Pending

3. Classification:

Title 21, Code of Federal Regulations, § 892.2020 & § 892.2050. Now proposed exempt, final rule pending.

ProCode: 90-LMD & 90-LLZ

4. Equivalent Device(s):

Acculmage™ Viewer Products, K961023, by Acculmage, Inc.

The referenced system is substantially equivalent to *ISSA PHAROS* in terms of basic design, features and intended use.

5. Description of the Device:

The *ISSA™ Imaging and PHAROS Communication Products* is a tightly integrated package of software elements designed to provide:

- DICOM compliant telemedicine viewer interface
- 2D viewer of all stored medical images
- Telemedicine communication system

In general terms, *ISSA PHAROS* contains two software applications, Issa and Pharos. Both belong to the group of software products for medical image management and manipulation. Applications are designed to fit equally to small medical units, such as imaging clinics or general practice clinics, and to large medical units such as hospitals or hospital departments. Image management and manipulation here means acquisition, archival, processing and analysis and transmission or distribution.

6. Contact Person:

Adil Džubur, B.Sc.
 VAMS Tec, d.o.o
 Petriceva 7, 10000
 ZAGREB, CROATIA
 011.385.1.4872.155

7. Submission Correspondent:

Mr. David W. Schlerf
 Buckman Company, Inc.
 200 Gregory Lane, Suite C-100
 Pleasant Hill, CA 94523-3389
 925.356.2640 VOX - 925.356.2654 FAX

8. Performance Standards:

There are no applicable FDA mandated performance standards for this device. However, voluntary standards such as DICOM 3.0, and ISO/IEC 10918-1 Digital Compression and Coding of Continuous-Tone Still Images (known as JPEG) and various in-house Standard Operating Procedures and vendor qualification procedures are in place and utilized in the production of the software. The software designed to control and manipulate the diagnostic images follows the international standard ISO/IEC 12207: 1995 Information technology - Software Life Cycle Processes. In accordance with that standard, the level of concern relative to this software has been determined using the decision tree provided in Version 1 of the FDA Software Guidance.

9. Software Information:

The software described in the submission was developed, tested and validated in accordance with written Verification and Validation procedures. The software development process and the supporting procedures identify responsible individuals within VAMS Tec who develop and approve product specifications, coding and testing. No known hazardous procedures were detected during verification and testing that would be the consequence of software operation. Failure of the system can cause corruption of the archive. Auto-repair feature is included in the software. Archive backup intervals are adjustable by administrator from 1 day to many days.

10. Hardware Requirements: (Minimum)

1. Pentium based PC
2. 64 MB of RAM
3. 4.1.GB hard disc
4. 24x CD-ROM
5. UVGA Monitor
6. MS IntelliMouse with wheel
7. USB keyboard
8. Win95/98 & Windows NT4.0.



FEB 14 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850VAMS Tec, D.o.o.
c/o Mr. David W. Schlerf
Official Correspondent
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389Re: K994054
Issa Pharos (Picture Archiving and
Communications System)
Dated: November 19, 1999
Received: November 30, 1999
Regulatory Class: II
21 CFR §892.2050/Procode: 90 LLZ

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K994054

Device Name: *ISSA PHAROS*

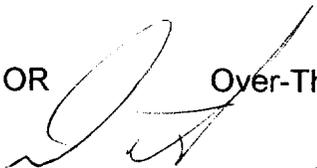
Indications For Use:

Acquire, store, transmit, and display medical images and patient reports of various types. Teleradiology image acquisition, distribution, archive and viewing.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR



Over-The-Counter Use
(Optional format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994054