K993802

JAN 18 2000

EXHIBIT 2

ContextVision AB
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CONTACT: Magnus Aurell

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: SharpView
   Classification Name: Picture Archiving and Communications system
   Product Code LNH
   Common/Usual Name: MRI Image Enhancement System

2. Equivalent legally marketed devices: This product is similar in design and function to the IES Image Enhancement System, K922470

3. Indications for Use (intended use) The SharpView Image Enhancement System is used for the intended for use by a qualified/trained technologist for transfer, storage, enhancement, and viewing of MRI images.

4. Description of the Device: The product is a kit containing software and hardware (PCI graphics processor board) which is intended to be installed on a personal computer. Typically the personal computer receives MRI images in DICOM 3 format over a network connection. The received image is stored locally, then accessed, then enhanced by the software/hardware combination, then stored in the enhanced format. The original file can still be accessed and is not modified.

5. Safety and Effectiveness, comparison to predicate device. The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart

Characteristic	IES Image Enhancement System (K922470)	SharpView Image Enhancement System
Intended Use:	The Image Enhancement System is intended for use by a qualified/trained technologist for transfer, storage, enhancement, and viewing of MRI images.	SAME
Physical characteristics:		
Computer	Sun computer (MRI console)	PC compatible
Operating system	Unix	Windows 98, NT 4.0
Storage	Hard disk or Optical Disk	Hard disk or any compatible PC method: Optical, CDROM, Tape
Image processing board	MIP-S	MIP-PCI
Software core	GOP® Enhancement software	SAME
Image input	Direct from MRI console (product is installed in MRI unit)	DICOM 3

7. **Conclusion**

After analyzing both bench and user testing data, it is the conclusion of Contextvision AB SharpView Image Enhancement System is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2000

Constance Bundy
ContextVision AB
c/o C.G. Bundy Associates
6470 Riverview Terrace
Minneapolis, MN 55432

Re: K993802
SharpView Image Enhancement System
Dated: November 1, 1999
Received: November 9, 1999
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Ms. Bundy:

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

i) Indications for Use

510(k) Number K993802

Device Name:

Indications for Use: The SharpView Image Enhancement System is intended for use by a qualified/trained technologist for transfer, storage, enhancement, and viewing of MRI images.

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993802

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)