K02 4028

EXHIBIT 2

JAN 2 4 2003

ContextVision AB
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CONTACT: Kent Strandlund

November 29, 2002

510(k) Summary of Safety and Effectiveness

1. Identification of the device:
   Proprietary-Trade Name: SharpView
   Classification Name: Image Processing, System
   Product code: 90LLZ
   Common/Usual name: SharpView Image Enhancement System

2. Equivalent legally marketed devices: This product is similar in design and function to the ContextVision SharpView Image Enhancement System, K993802

3. Indications for Use (intended use); The SharpView Image Enhancement System is intended for use by a qualified/trained technologist for transfer, storage, enhancement, and viewing of multi-modality images from a variety of diagnosis imaging systems.

4. Description of the device: The product is a software or a kit containing software and hardware (Image processing board), which is intended to be installed on a personal computer. Typically the personal computer receives digital medical images in DICOM 3 format over a network connection. The enhanced and original image can be sent in DICOM 3 format over the network connection. The original file and the enhanced file can be kept locally if selected.

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

6. Substantial Equivalence Chart

Characteristics:	SharpView Image Enhancement System	SharpView Image Enhancement System, modified
Intended use:	The Image Enhancement System is intended for use by a qualified/trained technologist for transfer, storage, enhancement, and viewing of MRI images.	The Image Enhancement System is intended for use by a qualified/trained technologist for transfer, storage, enhancement, and viewing of multi-modality images.
Physical characteristics:		
Computer	PC compatible	Same
Operating system	Windows 98, NT 4.0	Windows 98, NT 4.0, 2000 and XP
Storage	Hard disk or any compatible PC method: Optical, CDROM, Tape	Same
Image processing board	MIP-PCI	Javelin (PCI-bus)
Software core	GOP® Enhancement software	Same (Trademark is the property of ContextVision)
Image input	DICOM 3	Same

7. Conclusion

After analysing both bench and user testing data, it is the conclusion of ContextVision AB that the multi-modality SharpView Image Enhancement System is as safe and effective as the predicate device, has few technological differences, and only a minor change to the indications for use compared with the predicate device, 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 2 4 2003

Mr. Kent Strandlund
Quality & Regulatory Affairs
ContextVision AB
Storgatan 24
SE-582 23 Linköping
SWEDEN

Re: K024028
Trade/Device Name: SharpView Image Enhancement System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: November 29, 2002
Received: December 6, 2002

Dear Mr. Strandlund:

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 Section 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 the 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" (21CFR Part 807.97) you may obtain. 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

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

j) Indications for Use

510(k) Number K024028

Device Name: SharpView Image Enhancement System

Indications for Use: The SharpView Image Enhancement System is intended for use by a qualified/trained technologist for transfer, storage, enhancement, and viewing of multi-modality images from a variety of diagnosis imaging systems.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024028