

NOV 19 2004

**510(k) Summary of Safety and Effectiveness**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared: September 22, 2004

Submitter's Information: 21 CFR 807.92(a)(1)

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3mensio Medical Imaging BV  
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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

|                        |   |
|------------------------|---|
| Trade Name:            | 3viseon™                                |
| Common Name:           | Picture Archiving Communications System |
| Device Classification: | 892.2050 LLZ                            |
| Name:                  | System, Image Processing                |

Predicate Device: 21 CFR 807.92(a)(3)

|                                   |                                     |
|-----------------------------------|-------------------------------------|
| Device Classification Name        | System, Image Processing, Radiology |
| Regulation Number                 | 892.2050                            |
| 510(k) Number                     | K992654                             |
| Device Name                       | Plug™ n View 3D™                    |
| Applicant                         | Voxar Limited                       |
| Product Code                      | LLZ                                 |
| Decision                          | SUBSTANTIALLY EQUIVALENT (SE)       |
| Classification Advisory Committee | Radiology                           |
| Review Advisory Committee         | Radiology                           |

Device Description: 21 CFR 807.92(a)(4)

3viseon™ is a software based application for picture archiving and communications system that provides users with capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images (including digital Mammograms).

The 3viseon software allows you to select patient series from various data sources, view them in 2D or 3D mode and process the images with the help of a comprehensive set of tools:

- Data Management – for a detailed description on how to select patient studies from one or more data sources;

- 2D Viewing Mode – for a detailed description on how to view images in 2D mode and process them;
- 3D Viewing Mode – for 3D imaging.

Indications for Use: 21 CFR 807 92(a)(5)

3viseon™ is a device that receives medical images (including mammograms) and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.

Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA. Typical users of this system are trained professionals, i.e. physicians, radiologists, nurses, medical technicians, and assistants.

Technological Characteristics: 21 CFR 807 92(a)(6)

3viseon™ is medical device image software that is used with computer hardware in a picture archiving and communications system user environment. The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification 3viseon™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

3viseon™ will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards has been classified as "minor".



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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3mensio Medical Imaging BV  
% Mr. N. E. Devine, Jr.  
Responsible Third Party Official  
Entela, Inc.  
3033 Madison Ave. SE  
GRAND RAPIDS MI 49548

Re: K043097  
Trade/Device Name: 3viseon™  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and  
communications system  
Regulatory Class: II  
Product Code: 90 LLZ  
Dated: October 29, 2004  
Received: November 9, 2004

Dear Mr. Devine:

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 (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 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.

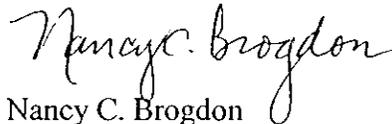
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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 this letter:

|                 |                                  |              |
|-----------------|----------------------------------|--------------|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology)          | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology)                      | 240-276-0120 |
| Other           |                                  | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

Enclosure

(Indications for Use Form)

510(k) Number: K043097

Device Name: **3viseon™**

Indications for Use:

**3viseon™** is a device that receives medical images (including mammograms) and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

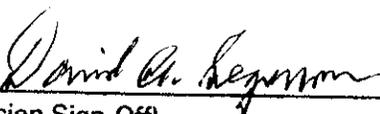
Typical users of this system are trained professionals, i.e. physicians, radiologists, nurses, medical technicians, and assistants.

Prescription Use ✓ ~~AND/OR~~ Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K043097