K974755

510-k Summary

Pursuant to 21 CFR 807.92 the following summary is submitted.

MAR - 4 1998

1. Submitter's name-
IMD Systems, Inc.
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November 25, 1997

2. DynaVue 3-D spinning Image System (3DSI) for use as an accessory to MRI's, CAT Scans, DSA and Ultrasound systems and to permit individual sale of 3DSI for permitting this data to be viewed in true 3-D.

3. We are claiming substantial equivalence to the Voxel System manufactured by Voxel Digital Holography which is used in a similar manner and permits 3-D imaging just as our 3DSI system does. We are also claiming substantial equivalence to the manner in which the 3D Imaging is generated as the Endolive System (3 D Endoscope) produced by Carl Zeiss Germany.

4. The DynaVue 3-D spinning Image System (3DSI) takes a stream of images (frames) and as a first step duplicates the frames and pairs them by delaying one image stream. This is done by the 3DSI's field delay circuit.

With the paired image, the system has now created a parallax. In order to see a 3-D image the system creates a sequence of left or right images on the screen. After the paired images are coded " left" and " right", the information is transmitted to a controller/emitter. The emitter converts the left and right information into an infrared signal which activates the left or right shutter. The emitted 3-D images are observed with active viewing eyewear.

The system can also be used with an active monitor screen, the same principles as above apply except that the infrared emitter is not needed and the active viewing eyewear is replaced by passive polarizing glasses.

5. This device will be used in the same manner as the Voxel System is used, except that the 3DSI may permit real time viewing of the three dimensional data. These types of devices are used to aid the physician in visualizing the anatomy of the patient and because they provide three dimensional images, they permit the physician to see tumors and other ailments which may have otherwise been difficult to see. The system does not take the place of the physician they are only a tool used to assist the physician with his diagnosis. They do not make the diagnosis for him. They may also be used to assist the surgeon in visualizing the surgical site better prior to surgery. Decisions about what to do and how to perform a procedure still rest firmly with the surgeon. This system incorporates the intended uses of the Voxel system and now our system may also be used real time.

6. The 3DSI is substantially equivalent to the Voxel system made by Voxel Digital Holography. Both of these systems are used to aid the physician in visualizing the anatomy of the patient. They both permit the physician to see tumors and other ailments which may have otherwise been difficult to see.

The primary differences between the two systems are the hardware that the two systems use to project the image. The Voxel system takes the slices of three dimensional data and layers them on Voxfilm. This film is then placed in a special viewing box which the physician can look at and even walk around to view in 3-D.

The 3DSI uses a Field Delay Converter which takes the three dimensional data and delays and pairs it into two streams. This data is then fed into a monitor. If it is not an active monitor an emitter is used and the person viewing must use active eyewear. If an active monitor is used then passive polarizing glasses may be used. The image that is projected is a true 3-D image which can also show motion. While the hardware is different the image that is projected and the intended uses of the systems are virtually the same.

The 3DSI and the Zeiss Endolive system are substantially equivalent in the manner in which they project 3-D. They use much of the same hardware and both rely on the shuttering effect and glasses to view the 3-D image. The Endolive system is an endoscope that is invasive, the 3DSI is not invasive at all, it never contacts the patient. The 3DSI relies on a Field Delay Converter while the Endolive relies on another hardware piece to generate the delay. Other than this the systems are very similar in their projection and viewing of the 3-D image. We do not claim any of the intended uses of the Zeiss Endolive system we are only claiming substantial equivalence to the method of producing the 3-D image.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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Kenneth M. Nicoll
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Re: K974755
Dyna Vue 3-D Imaging System
Dated: November 25, 1997
Received: December 19, 1997
Regulatory class: Unclassified
Procode: 90 LLZ

MAR - 4 1998

Dear Mr. Nicoll:

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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CONFIDENTIAL

INDICATIONS

510-k Number: ~~No K number yet~~, ~~new submission~~. K974755

Device Name: DynaVue 3-D Spinning Image System

Indications For Use:

This device will be used in the same manner as all three dimensional imaging products are used, similar to the Voxel System. It can be used with any two and three dimensional spinning image data such as MRI, CAT, DSA and Ultrasound produced data and converts the data into complete and real 3D images in rotational and static fashion. The device is used to aid the surgeon by permitting more precise morphological diagnosis especially in aneurysms, atherosclerotic lesions and bile duct carcinomas due to the improved view of the data. It may also facilitate highly selective interventional procedures for vascular surgeons because of the improved three dimensional vascular road map the physician sees. The system does not take the place of the physician it is only a tool to assist the physician in his diagnosis, it does not make the diagnosis for him. Decisions about what to do and how to perform a procedure rest firmly with the physician.

This device is used primarily by physicians and health care workers, and is normally used under the supervision of a physician. It is not sold to the general public but may be available as a teaching tool to Universities and Medical Schools without the requirement of physician supervision.

David A. Bryan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974755

Prescription Use David A. Bryan
(Per 21 CFR 801.109)