K012779

NOV 02 2001

SECTION 10

510(k) SUMMARY

This 510(k) summary of safety and effectiveness for iConnection 3D is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: HInnovation, Inc.

Address: 10437 Innovation Drive
Suite 236
Wauwatosa, WI 53226-4815

Contact Person: Y. Isabelle Sun, Ph.D.
Vice President, Business Development

Telephone: 414-453-7881
253-550-0903 (fax)

Preparation Date: August 2001
(of the Summary)

Device Name: iConnection 3D

Common Name: Picture Archiving and Communication System

Classification: Class II Medical Device; (21 CFR 892.2050)
Product Code: LLZ
Panel: 90

Predicate devices: Voxar Limited (PLUG 'N VIEW 3D, Version 1.0; K992654) and Applicare Medical Imaging, B.V, as described in K982862 and K962699;

Device description: iConnection 3D is a picture archiving and communications system as described in 21 CFR 892.2050.

Indications: iConnection 3D is a software application intended for integrated processing and distribution of 2D and 3D digitized data derived from CT and MRI (and others) scans for use by radiologists, clinicians, and other professionals to acquire, process, render, review, store, print, and distribute DICOM 3.0 compliant images utilizing standard PC hardware with MS 98, NT, or MS 2000 operating systems.

"CAUTION: Federal (US) law restricts the use of this device to licensed professionals."

Performance Data: None required. The claim of substantial equivalence is based on comparisons of intended use(s) and specifications/functions of the cited predicate devices.

CONCLUSION: Based on the information in the notification HInnovation, Inc. believes that iConnection 3D is substantially equivalent to the claimed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 2 2001

Hui Hu, Ph.D.
President and CEO
Hinnovation, Inc.
10437 Innovation Drive, Suite 236
WAUWATOSA WI 53226

Re: K012779
Trade/Device Name: iConnection 3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 20, 2001
Received: August 20, 2001

Dear Dr. Hu:

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 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:

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" (21 CFR Part 807.97). 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

K012779

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SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K01 2779

Device Name: iConnection 3D

Indications for Use Statement:

iConnection 3D is a software application intended for integrated processing and distribution of 2D and 3D digitized data derived from CT and MRI (and others) scans for use by radiologists, clinicians, and other professionals to acquire, process, render, review, store, print, and distribute DICOM 3.0 compliant images utilizing standard PC hardware with MS 98, NT, or MS 2000 operating systems.

CAUTION: Federal (US) law restricts the use of this device to licensed professionals.

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The Counter Use ___
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012779