Section 5: 510(k) Summary

K061813

[Submitted pursuant to 21 CFR 807.92(a). All data included in this document are accurate and complete to the best of DSC's knowledge.]

1. Submitter Information

AUG 18 2006

Submitter: Direx Systems Corporation
437 Turnpike Street
Canton
MA 02021

Telephone: (339) 502-6013
Fax: (339) 502-6018
Contact Person Larisa Gershtein
QA Manager

Contact Person e-mail address: lgershtein@direxusa.com

2. Device

Trade/Proprietary Name: Vert-X

Classification Name: System, x-ray, fluoroscopic, image-intensified.

Regulation Number: 21 CFR 892.1650

Regulatory Class: Class II (special controls)

Product code: 90 JAA

Panel: Radiology

3. Predicate Devices

Direx 3Dscope (K053640)

4. Intended Use:

Vert-X is a mobile apparatus used for fluoroscopic examination of a patient.

5. Description

Vert-X is a compact, mobile fluoroscopic system designed for general fluoroscopic imaging. *Vert-X* acquires, processes, displays, and stores x-ray images, for image diagnosis.

6. Clinical Tests

No clinical tests were performed

7. Performance Testing

Vert-X was tested according to the following standards:

IEC 60601-1 (1998) + A1(1991) + A2(1995)

IEC 60601-1-1 (2000)

IEC 60601-1-2 (2001) + A1 (2004)

IEC 60601-1-3 (1994)

IEC 60601-2-7 (1998)

IEC 60601-1-4 (1996) + A1 (1999)

ISO 14971 (2000)

FDA CDRH 21CFR 1020.30

FDA CDRH 21CFR 1020.32

6. Substantial Equivalence

Vert-X is meets the requirements for a special 510(k) by the virtue of being a minor modification, which does not change the intended use, fundamental technology or reduce safety and effectiveness, of the Company's predicate device, *3Dscope*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 1 8 2006

Ms. Larisa Gershtein
QA Manager
Direx Systems Corp.
437 Turnpike Street
CANTON MA 02021

Re: K061873
Trade/Device Name: Vert-X
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: June 27, 2006
Received: July 3, 2006

Dear Ms. Gershtein:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

DIREX
SYSTEMS CORP.

Section 4: Indications for Use Statement

Indications for Use STATEMENT

510(k) Number (if known): K061873

Device Name:

Vert-X

Indications for Use:

Vert-X is a mobile apparatus used for fluoroscopic examination of a patient.

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

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

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061873

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