K051028

F. 510(k) Summary

F.1 Manufacturing Establishment and Contact Information

MAY 13 2005

F.1.1 Manufacturer Name and Address:

Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730

F.1.2 Establishment Registration Number:

1221300

F.1.3 Name, Title, and Telephone Number of Contact:

Daniel F. Phelan
Senior Regulatory Affairs Specialist
(781) 999-7300

F.2 Device Identification

F.2.1 Device Trade Name:

Fluoroscan InSight Mini C-Arm Fluoroscopic Imaging System

F.2.2 Common / Usual Name:

Fluoroscopic Imaging System

F.2.3 Proposed Intended Use:

The Fluoroscan InSight is a Mini C-Arm Fluoroscopic Imaging System designed to provide physicians with general fluoroscopic visualization of a patient, including, but not limited to surgical orthopedic and podiatry use, critical and emergency care procedures, and light anatomy imaging situations.

F.3 Device Classification

F.3.1 Classification:

Class II

F.3.2 Classification Name and Rule:

Image-Intensified Fluoroscopic X-Ray System, 21 CFR 892.1650

F.3.3 Classification Panel:

Radiology

F.3.4 Product Code:

90 JAA

F.3.5 Predicate Device

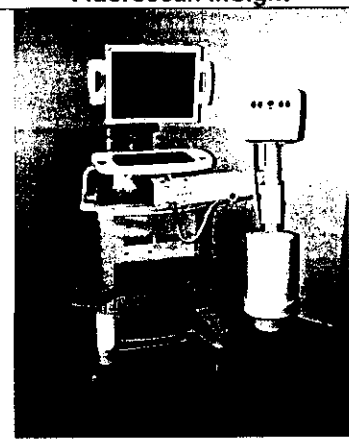
510(k) No.: K974058

Trade Name: FS IV Mini C- Arm System

SE Date: January 12, 1998.

Manufacturer: Hologic, Inc.

F.4 Substantial Equivalence

	Fluoroscan Premier(FS-IV)	Fluoroscan InSight
		
510(k) Number	K974058	[redacted]
Indications for Use	Mini C-Arm Fluoroscopic Imaging System designed to provide physicians with general fluoroscopic visualization of a patient, including, but not limited to surgical orthopedic and podiatry use, critical and emergency care procedures, and light anatomy imaging situations	Same
Dimensions (HxWxD)	60" (152cm) x 36" (91cm) x 32" (81cm)	65" (165.1cm) x 35" (88.9cm) x 35" (88.9cm)
Weight (maximum)	500 lbs (227 kg)	650 lbs (295.46 kg)
Voltage (nominal)	100/120/220/240 Single Phase	Same
Frequency	50/60 Hz	Same
Source-Image receptor distance	17.5" (44cm)	Same
X-Ray Source	Grounded anode x-ray tube 0.005" (0.127 mm) Beryllium	Same
Beam Filtration	Stainless Steel with Al equivalence ≥ 2.5mm	Same
Focal Spot	0.0018" (0.045mm) @ 7.5 watts	Same
Field of View	Operator selectable, 4" or 6" collimation (10.16 cm or 15.24 cm) at plane of Image Intensifier	Same
Rated peak tube potential	75kVp	Same
Tube kVp range	40 to 75kVp	Same
Tolerances	kVp ± 5% mA ± 8% ≤ 0.035mA mA ± 5% ≥ 0.035mA	Same
Maximum duty cycle at 75 kVp/0.100mA	50%	Same
Video Camera	Analog	Digital
System computer minimum requirements	850 MHz processor 128 MB RAM CD-ROM 20 GB HDD 3.5" Floppy	2.4 GHz processor 512 MB RAM Serial 80 GB HDD DVD RAM drive 3.5" Floppy drive
Operating System	Windows NT Embedded	Windows XP
Display	Dual 15" Hi-Res CRT	Medical grade 2 Mega Pixel 19.8" Monochrome Flat LCD
Input Devices	Keyboard, Footswitch, Touch Screen	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2005

Mr. Daniel F. Phelan
Senior Regulatory Affairs Specialist
HOLOGIC, Inc.
35 Crosby Drive
BEDFORD MA 01730

Re: K051025
Trade/Device Name: Fluoroscan InSight Mini C-Arm Fluoroscopic Imaging System
Regulation Number: 21 CFR §892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: April 21, 2005
Received: April 25, 2005

Dear Mr. Phelan:

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

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

Enclosure

A.2 Indications for Use Statement

510(k) Number (if known): K051025

Device Name: Fluoroscan InSight Mini C-Arm Fluoroscopic Imaging System

Indications for Use:

The Fluoroscan InSight is a Mini C-Arm Fluoroscopic Imaging System designed to provide physicians with general fluoroscopic visualization of a patient, including, but not limited to surgical orthopedic and podiatry use, critical and emergency care procedures, and light anatomy imaging situations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use

(Per 21 CFR 801.109) (Optional Format 1)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051025