K974058

510(K) SUMMARY
FS IV Mini C-arm System

JAN 12 1998

Submitter Name:	Hologic, Inc.
Submitter Address:	590 Lincoln Street Waltham, MA 02154
Contact Person:	Nandini Murthy, Regulatory Scientist
Phone Number:	(781) 890-2300
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Date Prepared:	Oct 24, 1997
Device Trade Name:	FS IV Mini C-arm System
Device Common Name:	Fluoroscopic imaging system
Predicate Devices:	Fluoroscan III Mini C-arm System OEC Series 6600 Digital Mobile C-arm XiScan Dual Digital Mini C-arm Lunar ORCA Orthopedic C-arm
Device Description:	The FS IV Mini C-arm system is a compact, mobile C-arm specifically designed for X-ray imaging.
Intended Use:	The FS IV Mini C-arm system is designed to provide physicians with general fluoroscopic visualization of a patient including, but not limited to, surgical orthopedic and podiatric, critical and emergency care procedures and light anatomy imaging situations.
Performance Data:	Results of bench testing for the FS IV mini C-arm imaging system indicates conformance to all applicable performance standards promulgated by the FDA for fluoroscopic imaging systems.
Conclusion:	Based on a comparison to other devices determined to be substantially equivalent through the 510(k) premarket notification process and the claim that the FS IV device meets the federal performance standard for fluoroscopic x-ray systems per 21 CFR 1020.30-1020.32, Hologic, Inc. concludes that the FS IV mini C-arm system is as safe, as effective and performs as well as other legally marketed mini C-arm devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 1998

Nandini Murthy, RAC
Regulatory Scientist
Hologic, Inc.
590 Lincoln Street
Waltham, MA 02154

Re: K974058
FS IV Mini C-arm System
Dated: Ocotober 24, 1997
Received: October 27, 1997
Regulatory class: II
21 CFR 892.1650/Procode: 90 JAA

Dear Ms. Murthy:

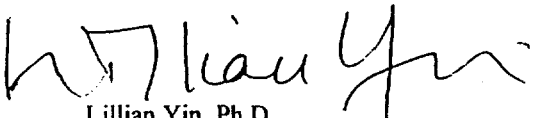
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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/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

510(k) Number (if known): K974058

Device Name: FS IV MINI C-ARM SYSTEM

Indications For Use:

The FS IV Mini C-arm system is designed to provide physicians with general fluoroscopic visualization of a patient including, but not limited to, surgical orthopedic and podiatric, critical and emergency care procedures and light anatomy imaging situations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974058

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)