



SEP 30 2002

**Fischer Industries Inc.®**

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**Section B – 510(K) Summary**

*K022154*

<b>Submitted by:</b>	Fischer Industries, Inc. 2630 Kaneville Court Geneva, IL 60134 Telephone: (630) 232-2803 Fax: (630) 232-2875
<b>Contact Person:</b>	Phil O'Keefe
<b>Date Submitted:</b>	6/11/02
<b>Trade Name of this Device:</b>	Level 356 X-Ray Film Processor
<b>Common or Useful Name:</b>	Film Processor
<b>Classification Name:</b>	Automatic Radiographic Film Processor
<b>Substantial Equivalence:</b>	Futura System 30 DX K940112 4/11/95
<b>Description of Device:</b>	Automatic Radiographic Film Processor
<b>Intended Use:</b>	The Level 356 X-Ray Film Processor is a diagnostic device intended to be used to develop, fix, wash, and dry automatically and continuously film exposed for medical and dental purposes. This is the sole purpose of this device.
<b>Comparison Summary:</b>	This film processor is operates like most predicate devices in that it uses a series of transport rollers to pull film through a series of open developer solution, fixer solution, and wash water tanks. Developer and fixer solution temperature is controlled automatically by a computer board. No plumbing is required.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 30 2002

Mr. Philip J. O'Keefe  
Director of Engineering  
Fischer Industries, Inc.  
2630 Kaneville Court  
GENEVA IL 60134

Re: K022154  
Trade/Device Name: Level 356 X-Ray Film Processor  
Models MD and MD-D  
Regulation Number: 21 CFR §892.1900  
Regulation Name: Automatic radiographic film processor  
Regulatory Class: II  
Product Code: 90 IXW  
Dated: June 27, 2002  
Received: July 2, 2002

Dear Mr. O'Keefe:

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  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

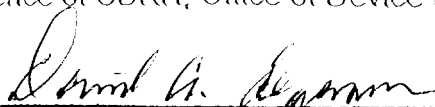
510(k) Number (if known): K022154

Device Name: Level 356 X-Ray Film Processor, Models MD & MD-D

Indications For Use: The Level 356 X-Ray Film Processor is an automatic radiographic film processor, a diagnostic device intended to develop, fix, wash, and dry automatically and continuously film exposed for medical and dental purposes. This is the sole purpose of this device.

(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,  
and Radiological Devices  
510(k) Number K022154

✓  
Prescription Use  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format)