K992818

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Section 7

PROTEC Medizintechnik GmbH & Co. KG • Lichtenberger Straße 35 • D-71720 Oberstenfeld

PROTEC
Processor-Technology
made in Germany

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510(k) Summary

From	e-mail	Telephone	Date
Contact Person Mr. Frank Baisch	frank.baisch@protec-med.com	+49-7062-9255-17	May 17, 1999

This Summary of Safety and Effectiveness is in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Device:

Common name: Automatic X-Ray Film Processor

Trade name: OPTIMAX
COMPACT 2

Classification name: Processor, Radiographic-Film, Automatic

Predicate Device:

The Predicate Device is a legally marketed, postamendments device:

K954345 DOOSAN DSP 3800 Automatic X-Ray Film Processor

Device Description

Due to the precise roller transport system, both sheet and roller films can be processed. The automatic film registration is activated immediately when a film is fed in. The transport system starts running. The film material is developed, fixed, rinsed and dried. With the easy to operate micro-processor, the processing conditions can be adjusted to suit the various film and chemical types. The developing solutions are temperature-regulated, circulated and automatically replenished. The feed width of the OPTIMAX is 35 cm, the bigger COMPACT 2 has 45 cm feed with. The smallest film format of both processors is 10*10 cm.

RA

Geschäftsführer:
Erhard Fichtner
Reg.Gericht Vaihingen/Enz

Bankverbindungen:
Baden-Württembergische Bank AG
Reutlingen
BLZ 640 200 30, Kto.-Nr. 1 401 737 000

Dresdner Bank AG, Filiale Heilbronn
BLZ 620 800 12, Kto.-Nr. 7 195 47300
Raiffeisenbank Oberstenfeld eG
BLZ 600 697 27, Kto.-Nr. 324 703 007

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Intended Use

The Automatic X-Ray Film Processor is intended to be used to process films exposed for medical purposes. The automatic and continuous process contains developing, fixing, washing and drying of films.

This may be used in all general radiographic, diagnostic imaging procedures. Typical users of this system are trained medical professionals, including but not limited to physicians, nurses, and lab technicians.

Summary of Substantial Equivalence Comparison

The comparison of similarities and differences shows that the new device PROTEC Automatic X-Ray Film Processor, which is intended to market and the predicate device:

1. have the same intended use
2. have the same target user group
3. have the same technological characteristics

There are no new questions about safety and effectiveness. The new device is as safe and effective as the predicate device.

The Automatic X-Ray Film Processor is substantially equivalent to the DOOSAN DSP 3800 Automatic X-Ray Film Processor.

Technological Characteristics

The photographic processing (developing) technique employed by the Automatic X-Ray Film Processor is the same as the predicate device. The film medium is mechanically transported for immersion in two chemical baths (developer and fixer), is rinsed in water, dried, and then ejected for viewing. The processors use mechanical rollers and guides for transportation, the solutions are temperature-regulated, circulated and automatically replenished, and same additional functions (anti-crystallization cycle, stand-by mode). Both are controlled by an integrated software.

PROTEC Medizintechnik GmbH & Co KG

Frank Baisch

(R&D Manager)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 1999

PROTEC Medizintechnik GmbH & Co. KG
C/O Carole Stamp
TUV Product Service, Inc.
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

RE: K992818
OPTIMAX/COMPACT 2
Dated: August 19, 1999
Received: August 20, 1999
Regulatory Class: II
21 CFR 892.1900/Procode: 90 IXW

Dear Ms. Stamp:

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 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). 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 2

510(k) Number (if known): _____

Device Name: Automatic X-Ray Film Processor

Indications For Use:

The Automatic X-Ray Film Processor is intended to be used to process films exposed for medical purposes. The automatic and continuous process contains developing, fixing, washing and drying of films.

This may be used in all general radiographic, diagnostic imaging procedures.

Typical users of this system are trained medical professionals, including but not limited to physicians, nurses, and lab technicians.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992818

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

(Optional Format 1-2-96)