Section 7

PROTEC medical systems

AUG 21 2009

PROTEC GmbH & Co. KG – Lichtenberger Str. 35 – 71720 Oberstenfeld

510(k) Summary

K091628/S001

PROTEC GmbH & Co. KG
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From	e-mail	Telephone	Date
Contact Person Mr. Jochen Krupp	jochen.krupp@protec-med.com	+49-7062-9255-25	October 17, 2007

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®, ECOMAX™
COMPACT™ 2, OPTIMAX® 2010

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®, OPTIMAX® 2010 and ECOMAX™ is 35 cm, the bigger COMPACT™ 2 has 45 cm feed with. The smallest film format of all processors is 10*10 cm.

p. 1 of 2

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). All are controlled by an integrated software.

PROTEC GmbH & Co KG

Jochen Krupp
(Technical Manager Analogue Systems)

p. 2 of 2

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AUG 21 2009

Mr. Jochen Krupp
Technical Manager Analogue Systems
PROTEC GmbH & Co., KG
Lichtenberger Straβe 35
Oberstenfeld, Baden-Württemburg 71720
GERMANY

Re: K091628
Trade/Device Name: Optimax, Compact 2, Optimax 2010, Ecomax
Regulation Number: 21 CFR 892.1900
Regulation Name: Automatic radiographic film processor
Regulatory Class: II
Product Code: IXW
Dated: June 29, 2009
Received: July 2, 2009

Dear Mr. Krupp:

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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091628

Device Name: OPTIMAX, COMPACT 2, OPTIMAX 2010, ECOMAX

Indications For Use:

OPTIMAX, COMPACT 2, OPTIMAX 2010, ECOMAX are all Automatic X-Ray Film Processors (Regulation No. 892.1900).

The devices mentioned above are 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.

PROTEC

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Prescription Use ✓ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 K091628