

JUN 13 1997

510(k) Summary

K971081

HEK

Common/Classification Name: Radiation Therapy Beam-Shaping Device, 21
CFR 892.5710

Sponsor: HEK Medizintechnik GmgH
Kaninchenborn 24-28
Postfach 1832
D-23560 Lübeck
GERMANY

Tel: (+49) 451 5300444
FAX: (+49) 451 5300450

Contact: Reinhard Schröder

Prepared: March 13, 1997

A. LEGALLY MARKETED PREDICATE DEVICES

The **AUTIMO 2-D System** is substantially equivalent to its predecessor device currently marketed by HEK Medizintechnik, the **MCP-70-SE** (K844180).

B. DEVICE DESCRIPTION

The **AUTIMO 2-D** model is a computer-controlled cutting tool to produce customized shielding blocks for use in radiotherapy. The computer accepts files from existing treatment-planning system operating on a LAN. The GE-Target, Siemens Helax, and Theratronics Theraplan systems are examples of such treatment-planning software. The computer interprets the files from the planning system and communicates with the AUTIMO device through a serial port.

The 2-D model allows automatic hot-wire-cutting of styrofoam molds such as lung blocks and irregular sections.

C. INTENDED USE

The **2.0-D AUTIMO System** is intended for the fabrication and positioning in radiotherapy of irregular shielding blocks.

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D. TECHNOLOGICAL CHARACTERISTICS

The **2.0-D AUTIMO System** has the same technological characteristics as the predicate device. The AUTIMO is simply a modification with updated hardware and cosmetic changes from the predicate device.

E. TESTING

HEK Medizintechnik carried out testing to address the following issues:

- (1) electrical safety
- (2) eletromagnetic compatibility

The results from these tests supported the safety and effectiveness of the **2.0-D AUTIMO System** and demonstrates that it is substantially equivalent to the predicate device.

F. CONCLUSIONS

The HEK **AUTIMO** device has the *same* intended use and target population as the predicate device. HEK has demonstrated through its performance tests on the **2.0-D AUTIMO systems** and its comparison of **AUTIMO** characteristics with those of the predicate device that the **2.0-D AUTIMO system** is substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

HEK Medizintechnik, GmbH
c/o T. Whit Athey, Ph.D.
Senior Consultant
C. L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, MD 20852

JUN 13 1997

Re: K971001
GmbH AUTIMO 2-D Dose Modification System
Dated: March 19, 1997
Received: March 19, 1997
Regulatory Class: II
21 CFR 892.5710/Procode: 90 IXI

Dear Dr. Athey:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: AUTIMO 2-D

Indications For Use:

- * The 2-D AUTIMO system is intended for the fabrication and positioning in radiotherapy of individualized (irregular) shielding blocks.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Beggs
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971001

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

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