

# 510(k) Summary

K972016

HEK

DEC - 4 1997

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: April 2, 1997

## A. LEGALLY MARKETED PREDICATE DEVICES

The **AUTIMO 2.5-D and 3-D System** is substantially equivalent to its predecessor device currently marketed by HEK Medizintechnik, the **MCP-70-SE** (K844180).

## B. DEVICE DESCRIPTION

The **AUTIMO 2.5-D and 3-D** models are computer-controlled cutting tool systems for producing 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.

## C. INTENDED USE

The **2.5-D and 3-D AUTIMO Systems** are intended for the fabrication and positioning in radiotherapy of irregular shielding blocks, dose modifiers, and compensators.

## D. TECHNOLOGICAL CHARACTERISTICS

The **2.5-D and 3-D AUTIMO Systems** have the same technological

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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 **2.5-D and 3-D AUTIMO Systems** 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 **2.5-D and 3-D AUTIMO systems** and its comparison of **AUTIMO** characteristics with those of the predicate device that the **2.5 and 3-D AUTIMO systems** are substantially equivalent to the predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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T. Whit Athey, Ph.D.  
Senior Consultant  
C.L. McIntosh  
& Associates, Inc.  
12300 Twinbrook Parkway, Suite 625  
Rockville, Maryland 20852

Re: K972016  
AUTIMO 2.5-D Dose Modication System  
Dated: September 8, 1997  
Received: September 9, 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 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

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Director, Division of Reproductive,  
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Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K972016

Device Name: AUTIMO 2.5-D and 3.0-D

Indications For Use:

The **2.5 D and 3-D AUTIMO** systems are intended for the fabrication and positioning in radiotherapy of irregular shielding blocks, compensators, and dose modifiers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David L. Segerson  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K972016

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

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