



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 27 1996

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Ronald F. Lagerquist  
Regulatory Affairs Analyst  
Mentor Corporation  
5425 Hollister Avenue  
Santa Barbara, California 93111

Re: K963066  
Trade Name: Mentor Injection Port Detector (IPD)  
Regulatory Class: Unclassified  
Product Code: LCJ  
Dated: August 2, 1996  
Received: August 7, 1996

Dear Mr. Lagerquist:

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.

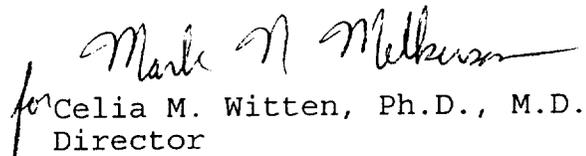
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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) 594-4595. 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 at (301) 443-6597.

Sincerely yours,

  
for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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510(k) Number (if known): K963066

Device Name: MENTOR Injection Port Detector

Indications For Use:

The Mentor Injection Port Detector is used to locate Mentor Tissue Expander remote and integral injection ports. The device is nonsterile and for postoperative use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Mark N. Melkus*

for  
CMW

(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K963066

Prescription Use             
(Per 21 CFR 801.109)

OR Over-The Counter Use           

(Optional Format 1-2-96)

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Executive Offices

5425 Hollister Avenue

Santa Barbara, CA 93111

(805) 681-6000

K963066

### 510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

SEP 27 1996

The assigned 510(k) number is:

Submitted by: Ronald F. Lagerquist  
Regulatory Affairs Analyst  
Mentor Corporation  
5425 Hollister Ave.  
Santa Barbara, CA 93111

Telephone: (805) 681-6000

FAX: (805) 681-6004

Date Prepared: August 2, 1996

#### Device Name

Proprietary Name: Mentor Injection Port Detector

Common Name: Injection Port Detector

#### Substantial Equivalence Claim

The Mentor H/S Injection Port Detector is similar in indications, design and features to the Mentor Accu-Tec™ Injection Port Detector (K905484).

#### Indications For Use

The Mentor H/S Injection Port Detector is used to detect Mentor Tissue Expander remote and integral injection ports. The device is nonsterile and for postoperative use only.

#### Device Description

The Mentor H/S Injection Port Detector is a hand-held battery operated, rechargeable unit which detects the stainless steel needle guard located inside remote and integral tissue expander injection ports. When not in use, the device rests in a charging cradle to maintain full charge.

The device contains electro magnetic coils and circuitry which detects changing magnetic fields. The presence of an injection port near the coils causes a change in the magnetic field, which in turn induces a current in the coils. An LED display indicates when the center of the injection port has been located.

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