

EXHIBIT #1

JUL - 8 1997

510(K) SUMMARY

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

The assigned 510(k) number is: K972000

1. Submitter's Identification:

Ralph Lindel, D.C.
271-30 77th Avenue
New Hyde Park, NY 11040

Date Summary Prepared: May , 1997

2. Name of the Device:

X-Ray Assist Bar

3. Predicate Device Information:

Chest X-Support
Steady Rest™, Distributed by Cone Instruments
Whitmore Enterprises, Inc., Whitmore Ankle X-Ray Extension (AXE) K#933778

4. Device Description:

Lower bar adjusts and locks to the horizontal position for the patient to hold onto and adjusts down to the vertical position so it can be moved close to the wall and out of the way when not in use.

Once the lower bar is in the horizontal position, the handle can be loosened and the height adjustment bar can be raised or lowered as well as be moved left or right along the tracks to adjust for differing patient heights and arm lengths.

The device can have two sets of tracks; one on either side of the X-Ray bucky. The height adjustment bar/lower bar/front block/rear block assembly can be removed by removing the set screw in the stop block between the end of the tracks, sliding the height adjustment bar/lower bar/front block/rear block

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assembly off the tracks and then sliding it onto the second set of tracks and putting the set screw in the stop block at the end of the second set of tracks.

5. Intended Use:

This device is intended to accurately position the patient's body in a steady, precise position during X-Ray procedures (erect lateral thoracic, lateral lumbar, lateral chest and lateral abdomen plain film X-Rays).

6. Comparison to Predicate Devices:

a. Table of Comparison to Legally Marketed Device:

The following is a "Comparison Chart" outlining differences and similarities between the X-Ray Assist Bar and the Chest X-Support:

PARAMETER	X-RAY ASSIST BAR	CHEST X-SUPPORT
Indications for Use	Accurately position patient's body during X-Ray procedures	Same
Intended Use	Erect thoracic, lateral lumbar, lateral chest and lateral abdominal X-Rays	Lateral chest X-Rays
Materials	Delrin plastic Aluminum grade 6061 Foam (sponge) rubber sleeve for handle	Wood
Patient Adjustment	Yes	Yes
Adjusts for varying arm lengths	Yes	No
Not In Use Position	Inactive position	?
Secure Bar Lock Position	Yes-plus Double Lock	Yes
Height Adjustment	Yes-Sliding track	11 Height Adjustments

b. Discussion of Similarities and Differences:

The X-Ray Assist Bar is substantially equivalent in intended use to the Chest X-Support, as both are intended to accurately position the patient's body during X-Ray procedures. Materials of construction are different and the X-Ray Assist Bar does adjust for varying arm lengths, where the Chest X-Support does not. S&S X-Ray Products also markets a PLANET Thermoplastic Immobilization System, cleared under K#944040, however, this device is intended to be used in radiotherapy applications for patient head positioning and immobilization. Materials consist of a thermoplastic sheet, however, radiation build-up studies for Linac and Cobalt treatments were required for submission.

Whitmore Enterprises, Inc. markets the Whitmore Ankle X-Ray Extension (AXE) under K#933778. The AXE device is a portable, lightweight radiolucent device intended to position the foot and ankle during X-Ray. The device is intended to position the foot and ankle in a steady, precise position during X-Ray procedure (like the X-Ray Assist Bar). The differences in material between the AXE and X-Ray Assist Bar is that the X-Ray Assist Bar is constructed of aluminum, plastic and foam, whereas the AXE is constructed of a nylon and velcro design to conform to any size foot and a sling (socklight holder). The X-Ray Assist Bar does not allow a full 180° range of motion (allowing the foot to be positioned at any angle) as the AXE, however, the X-Ray Assist Bar does allow for patient adjustments, to include varying arm lengths.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Non-Applicable

8. Discussion of Clinical Tests Performed:

Non-Applicable

9. Conclusions:

The X-Ray Assist Bar has the same indications for use as a combination of all cited devices. There are differences in materials when compared to the predicate devices, and, in some, facilitators such as patient body adjustments. However, the X-Ray Assist Bar does not incorporate significant changes in intended use, method of operations, or design that could affect safety or effectiveness, therefore, the X-Ray Assist Bar is substantially equivalent to the cited predicates.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ralph D. Lindel, D.C.
c/o Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd., Suite 410
Great Neck, NY 11021

Re: K972000
X-Ray Assist Bar
Dated: May 29, 1997
Received: May 30, 1997
Regulatory Class: II
21 CFR 892.1680/Procode: 90 KPR

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Dear Ms. Goldstein-Falk:

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

510(k) Number (if known): K972000

Device Name: X-Ray Assist Bar

Indications For Use:

This device is intended to accurately position the patient's body in a steady, precise position during X-Ray procedures (erect lateral thoracic, lateral lumbar, lateral chest and lateral abdomen plain film X-Rays).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use



(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K972000