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K982612

510(k) Summary

Fred Dawson
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Santa Clara, Ca. 95050
800-533-3339
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11-4-97

ESP7 Venous Imager
(vein locator)

Liquid Crystal Vein Locator KZA 880.6970 class 1
Predicate device = "E-Z-Jector"

The "E-Z-Jector" used a video camera with liquid crystal display and sensed temperature variations in the skin as a means of locating veins which are otherwise not visible. The veins could be located on the LCD monitor for view as an aid in inserting an I.V. or drawing blood.

The "ESP7 Venous Image" is designed for the same purpose, to locate veins which are otherwise not visible to the naked eye. It uses a similar technology in that it uses a standard Video Camera and television monitor mounted on a roll around height and angle adjustable metal stand. The ESP7 Venous Image, however, uses an Infrared filter placed between the camera lens and the CCD to eliminate visible light from entering the camera but allowing infrared and ultra violet light to pass through to the monitor. An on board light source broadcasts a low intensity light beam on the subject. The light source is a common household incandescent 50 watt light bulb that illuminates from a wave length of 350 to 900 nanometers. The ultra violet in the below 450 range is absorbed by the melanin in the epidermis forming a translucent window for the infra red to pass through the skin and differentiate the blue or carbon dioxide carrying venous vessels from the other objects in view.

This device is for use in hospitals, clinics, and Doctor's offices. It uses a grounded 110v 60 cycle electrical source using a total of 150 watts. All electrical components are safe over the counter items. Thermal safety is not a problem as the 50 watt light bulb is protected by a double wall metal shield as is cool to the touch.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Fred Dawson
Ironmaster, Incorporated
1719 Grant Street
Santa Clara, California 95050

Re: K982612
Trade Name: "ESP7 Venous Image"
Regulatory Class: I
Product Code: KZA
Dated: July 23, 1998
Received: November 23, 1998

Dear Mr. Dawson:

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 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). 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 requirements, 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) 594-4692. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

The ESP7 Venous Imager is a non-invasive electronic visual aid device for the purpose of viewing of the human superficial venous vasculature.

Indications for use: 1) viewing the superficial venous vasculature as a visual aid in taking blood or inserting an I.V.

Patricia Cucente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982612

Over-the-Counter Use ✓