

K934700

MAR 16 1994

## SAFETY AND EFFECTIVENESS SUMMARY

### A. LABELING

Labeling complies with all applicable FDA requirements and meets or exceeds all labeling on the equivalent unit.

### B. LEAKAGE RADIATION FROM THE DIAGNOSTIC SOURCE

The leakage radiation from the diagnostic source does not exceed 100 milliroentgens in one hour when measured at leakage technique factors. This test is performed in compliance with current Federal regulations as outlined in 21 CFR subchapter J. Leakage is equal to or less than the equivalent device.

### C. BEAM QUALITY

The one half value layer of the source assembly is greater than 2.5 millimeters of aluminum. A test is performed on each unit to assure this. Filtration in the beam meets or exceeds the radiation in that of the equivalent device.

### D. REPRODUCIBILITY

The coefficient of variation of the radiation exposure is tested to be in compliance with current Federal regulations. The particular timer used is designed to have a variation of zero. The KvP is digitally selected and the mA is electronically regulated. This keeps the variation at or below that of the equivalent device.

E. PEAK TUBE POTENTIAL

The peak tube potential is digitally selected. Line voltage compensation is automatic. This eliminates the possibility of user errors which can occur with manual compensation. This feature allows for repeatability within a very small tolerance and meets or exceeds the repeatability of the equivalent device.

F. TUBE CURRENT

The tube current is controlled with an electronic milliamp compensation circuit. This maintains a stable tube current over a wide range of line voltages. The stability of this tube current is equal to or greater than that of the equivalent device.

G. EXPOSURE TIME

The timer uses a zero crossover detector and then counts the number of line pulses preset by the operator. Variation of the exposure time is therefore plus or minus zero pulses. This specification is equal to the equivalent device.

H. CENTER ALIGNMENT OF THE X-RAY FIELD AND RECEPTOR

This parameter is performed with the aid of a visible light beam. The equivalent device uses a typical light collimator. Both devices meet the Federal requirements in subdued light conditions. The 90P also can be used in bright light conditions such as might be necessary in field use.

## I. X-RAY FIELD SIZE

The size of the x-ray field is determined through the use of fixed collimation. These are collimator slide plates which drop into a frame. The slide plates are clearly marked as to what size field is produced at a given SID. Integrated into the front of the 90P is a retractable measuring tape used to determine the correct SID. The equivalent device uses a typical light collimator which defines a variable field under subdued light conditions. The 90P is sold standard with the laser collimator but is also capable of mounting a standard light collimator if so desired. We feel that the collimation, for portable outdoor applications is superior to the equivalent device.



Mr. Christopher E. Dare  
President  
Tempo Technology, Inc.  
2090 W. Dowell Road  
COLUMBIA CITY IN 46725

JAN 11 2012

Re: K934700

Trade/Device Name: Model 90P Portable Medical Diagnostic X-Ray System  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image-intensified Fluoroscopic x-ray system, mobile  
Regulatory Class: II  
Product Code: OXO  
Dated: February 1, 1994  
Received: February 8, 1994

Dear Mr. Dare:

This letter corrects our substantially equivalent letter of March 16, 1994.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval (PMA). 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. Please Note: CDRH does not evaluate information related to contact liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely Yours,



Mary S. Pastel, Sc.D.  
Director  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

Dear Mobile Fluoroscopic Device Manufacture:

This letter is to advise you that the FDA is in the process of updating the Product Codes for Mobile Fluoroscopic (OXO) devices to provide greater specificity regarding Mobile X-Ray devices. Product Codes, and their definitions, can be found in our classification database (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/classification.cfm>).

Mobile X-Ray devices have expanded greatly in scope since the creation of the first Mobile X-Ray devices product code, IZL, over 30 years ago: from standard mobile radiographic systems to sophisticated mobile interventional fluoroscopy devices. Because of the variety of mobile X-Ray devices currently on the market, the new product code will allow FDA to distinguish between the different types of mobile S-Ray devices marketed in the United States (U.S.), thereby allowing us to serve the Medical Imaging device industry and other stakeholders in a more clear and efficient manner.

**What you should do at this time:**

When preparing import paperwork, including your FDA Listing, **you must** continue to reference the “Current Product Codes” that are found on your 510(k) letter of substantial equivalence to avoid delays at the port of entry into the U.S. Do **not** use the “Planned Common Name and Planned Product Code” on any FDA Submission until the codes have been finalized for your device, and you have been **notified by FDA by receipt of a revised letter of substantial equivalence for your 510(k)(s). (Attached)**

**Need Further Clarifications?**

If you need further clarification on the issue or any other type of assistance in complying with FDA regulations, please contact the Division of Small Manufactures, International and Consumer Assistance, (DSMICA), by email at [DSMICA@CDRH.FDA.GOV](mailto:DSMICA@CDRH.FDA.GOV)

John Stigi  
Director  
Division of Small Manufactures, International and Consumer Assistance  
Office of Communication, Education and Radiation Programs  
Center for Devices and Radiological Health  
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