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510(k) Summary
[as required by 21 CFR 807.92]

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Submitter's Information [21 CFR 807.92(a)(1)]

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Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade names are Fuji Medical Dry Imager FM-DP 2636CR and Fuji Medical Dry Imager FM-DP 2636.

The device common names is medical image printer.

Predicate Device [21 CFR 807.92(a)(3)]

Fuji identifies the predicate device as the Fuji Medical Laser Imager Fuji FL-IM D. FDA assigned the predicate to regulatory class II citing 21 CFR § 892.1750.

FDA's accession number for the premarket notification for the predicate device is K945475. FDA cleared the marketing of the predicate device in a letter dated March 9, 1995.

Description of the Device [21 CFR 807.92(a)(4)]

The device accepts electrical image signals and produces hard copy images. The image signal source may be digital formatted image data from Fuji Computed Radiography image readers in the case of the FM-DP 2636CR, or unformatted image data from other imaging modalities (e.g. CT, MRI) in the case of the FM-DP 2636. The image signal source of for the FM-DP 2636 may be analog or digital.

The Fuji Medical Dry Imager uses the information in the image signals to control discrete elements in a linear thermal head which writes on the translating Fuji Medical Dry Imaging Film DI-AT, a thermal recording media. Unlike conventional laser imagers and multiformat cameras, there is no laser, cathode ray tube, or optics. Unlike conventional light-sensitive silver halide photographic media, the film requires no dark room, film processor, processing chemicals, water, drainage, or dryer ventilation, produces no chemical waste, and requires no space for chemical storage.

The major components of the imager are the film magazine, transport mechanics, imaging electronics, and thermal head.

Intended Use [21 CFR 807.92(a)(5)]

The indications for use of the Fuji Medical Dry Imagers is the production of hard copy images from medical image data.

Technological Characteristics [21 CFR 807.92(a)(6)]

The subject device, as the predicate, produces monochrome (black-and-white) gray-scale images from medical image data. The media and the technological characteristics are different.

The predicate device uses light sensitive silver halide photographic film as the recording medium. The subject device uses thermal recording film.

The predicate device exposes the film by translating it past a directly modulated scanning laser diode source. The exposed film is subsequently photographically processed to yield a visible image. In the subject device, the media is translated by a directly-modulated discrete-element thin-film linear thermal head. The action of heat on the media produces black dye in the medium, providing the density for the visual image without the wet chemical processing of the predicate.

Performance Data [21 CFR 807.92(b)(1)]

For medical image hard copy devices, important performance characteristics bearing on safety and effectiveness are spatial frequency response, gray scale resolution, and density uniformity.

The subject and predicate devices have similar spatial frequency response characteristics. The pixel size of the subject device (84.7 μ) produces a writing density of 11.8 pixels/mm or 300 dpi, compared to the writing density of the predicate, 10 pixels/mm. Square wave response (CTF) at 2.5 cycles/mm for both the subject and predicate devices is greater than 0.93.

The gray scale resolution of the subject (11-bit) and predicate (12-bit) devices both exceed the 10-bit gray scale range of Fuji Computed Radiography image data and judged adequate for the intended use.

The small-area density uniformity of the subject device, measured as Wiener Spectrum values, is slightly greater than the predicate. Both are one to two orders of magnitude greater than that of radiographic film-plus-screen mottle. Large-area density non-uniformity, as with the predicate, is judged not diagnostically significant. Both devices incorporate built-in density test patterns for use in maintaining density uniformity over time and with changes in media.

The devices comply with the UL 1950 *Standard for Safety of Information Technology Equipment, Including Electrical Business Equipment*.

Conclusion [21 CFR 807.92(b)(3)]

As the predicate, the subject devices have no patient contact. Nor do the subject devices control, monitor, or effect any devices directly connected to or effecting a patient. The images displayed by the subject devices are observed by medical personnel, offering ample opportunity for competent human intervention in the event of a failure.

While technologically different, the performance of the subject device in the areas of spatial and density resolution and density uniformity is similar to that of the predicate. The device, as the predicate, is provided with a test pattern generator and instructions for use to assure a consistent relationship between input signals and output film density (density and contrast).

The subject and predicate share the same certification of conformance to the UL 1950 *Standard for Safety of Information Technology Equipment, Including Electrical Business Equipment*.

We conclude that the subject devices are as safe and effective as the predicate device.