

## Declaration of FCR for Mammography FDA Approval

Manufacturer: FUJI PHOTO FILM CO., LTD.  
Address: 26-30 Nishiazabu 2-Chome, Minato-ku Tokyo 106-8620, JAPAN  
Product Name: Fuji Computed Radiography Mammography Suite (FCRMS)  
Approval Date: July 10, 2006  
PMA Number: P050014

We herewith declare that the above-mentioned products have received U.S. Food and Drug Administration (FDA) Pre-Market Approval (PMA).

FCRMS is a software installed in an already-FDA-cleared Fuji Computed Radiography (FCR) system to form the Fuji Computed Radiography for mammography (FCR<sub>m</sub>) device.

*(Extracted from the FDA webpage <http://www.fda.gov/cdrh/mda/docs/p050014.html>)*

FCR<sub>m</sub> consists of the following:

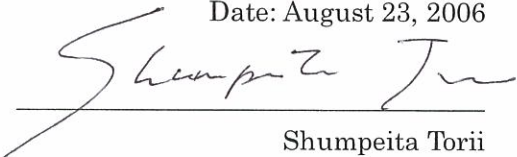
- Fuji dual-side Imaging Plates HR-BD in 18x24cm or 24x30cm sizes, for capturing the x-ray images and a corresponding number of Fuji IP Cassettes DM in the same sizes, for transporting the imaging plates;
- Fuji ClearView CS/ ClearView 1\* image reader configured for dual-side reading and 50-micrometer sampling pitch; for reading the x-ray from the imaging plate in the cassette; and
- A Fuji Flash Plus IIP CR console unite\*\*, the "acquisition" workstation with FCRMS installed.

*(Extracted from Essential Prescribing Information, listed as Labeling in the above webpage)*

\* Fuji ClearView CS is marketed as "FCR PROTECT CS" and ClearView 1 is marketed as "FCR PROTECT ONE" in countries outside of the US.

\*\* Fuji Flash Plus IIP CR console unit is marketed as "CR Console" in countries outside of the US.

Date: August 23, 2006



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