

K 963334

SEP 11 1998

Summary of Safety and Efficacy

510(k) Summary for the Jamieson Model 2100 Cine Processor
and the Kodak Cineflure Processor Model 2100

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

Submitter's Name

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Device Name and Classification

Trade name: Jamieson Model 2100 Cine Processor
Kodak Cineflure Processor Model 2100
Common Name: Black-and-white 35 mm cine film processor
Classification: Class II, Automatic Radiographic Film Processor, 21 CFR 892.1900

Predicate Device

The Model 2100 is substantially equivalent to the Jamieson JT/Kodak Ektacath, accepted on September 24, 1991, K# K913241/A.

Description of the Model 2100

The Model 2100 is a leader card black-and-white 35 mm cine film processor, most commonly used for developing cineangiogram films. The Model 2100 has four (4) tanks, the developer, fixer, wash, and dryer tanks. The Model 2100 is 58.5 inches long, 17 inches wide, and 43 inches high.

The Model 2100 has been altered to meet the electrical and safety requirements of the CE Medical Device Directive. Some minor modifications have been made to the transport assembly as well in response to customer preferences. None of the changes made adversely affect the safety or efficacy of the processor or can be considered new indications of use.