

**K972130 DISPOSABLE CAMERA COVER, ENCLOSED:
DISPOSABLE CAMERA COVER, PERFORATED: DISPOSABLE
MICROSCOPE COVER (VARIOUS):X-RAY COVR**

Oct 9, 1997
125 days to decision

K972130 · Product code: **IZJ** · Radiology
Source: <https://www.510kdatabase.net/k972130/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, X-ray, Fluorographic, Cine Or Spot (IZJ)
Date received	Jun 6, 1997
Decision date	Oct 9, 1997
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fairmontmedical
Location	Bayswater, Victoria, AU
Contact	JOANN MCBAIN
510(k) history	1 submissions · 1 cleared · 1997-1997

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k972130/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 20, 2026