

K884650 RESUBMITTED SCANORAMar 16, 1989
129 days to decisionK884650 · Product code: **IZF** · Radiology
Source: <https://www.510kdatabase.net/k884650/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomographic (IZF)
Date received	Nov 7, 1988
Decision date	Mar 16, 1989
Days to decision	129 days
Third-party review	No

APPLICANT

Company	Orion Corp.
Location	20101 Turku, FI
Contact	ENSIO KOSKENNURMI
510(k) history	21 submissions · 20 cleared · 1985-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k884650/>, 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 21, 2026