

K974877 CRANEX TOME CEPH, OR CRANEX TOMEMar 27, 1998
88 days to decisionK974877 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k974877/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Dec 29, 1997
Decision date	Mar 27, 1998
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Orion Corporation Soredex
Location	Helsinki, FI
Contact	KAI LANER
510(k) history	4 submissions · 4 cleared · 1988-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974877/> 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 19, 2026