

K053172 UNIVERSAL-X (USA) OR /KRYSTAL-X (EUROPE)Jun 9, 2006
207 days to decisionK053172 · Product code: **MUH** · Radiology
Source: <https://www.510kdatabase.net/k053172/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Nov 14, 2005
Decision date	Jun 9, 2006
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Owandy Sas
Location	New York, NY, US
Contact	OLIVIER MAURIER
510(k) history	1 submissions · 1 cleared · 2006-2006

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