

**K063837 SIGMA M**Jul 2, 2007  
188 days to decisionK063837 · Product code: **MUH** · Radiology  
Source: <https://www.510kdatabase.net/k063837/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Dec 26, 2006
Decision date	Jul 2, 2007
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Instrumentarium Dental, Palodex Group OY</b>
Location	Tuusula, FI
Contact	JOUNI ONNELA
510(k) history	5 submissions · 5 cleared · 2007-2014

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