

**K053040 PARACEM UNIVERSAL DC**Nov 9, 2005  
13 days to decisionK053040 · Product code: **EMA** · Dental  
Source: <https://www.510kdatabase.net/k053040/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Oct 27, 2005
Decision date	Nov 9, 2005
Days to decision	13 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coltene/Whaledent AG</b>
Location	New York, NY, US
Contact	HENRY J VOGELSTEIN
510(k) history	16 submissions · 16 cleared · 2005-2019

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