

**K152766 CharmFlex**Mar 8, 2016  
166 days to decisionK152766 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k152766/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Sep 24, 2015
Decision date	Mar 8, 2016
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dentkist, Inc.</b>
Location	Gunpo-Si, KR
Contact	SHIN HEANG LEE
510(k) history	2 submissions · 2 cleared · 2016-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152766/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026