

**K133527 SUFLEX PUTTY, SUFLEX HEAVY, SUFLEX MONO, SUFLEX LIGHT**

Mar 7, 2014  
112 days to decision

K133527 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k133527/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Nov 15, 2013
Decision date	Mar 7, 2014
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Osstem Germany GmbH</b>
Location	Fariless Hills, PA, US
Contact	PATRICK LIM
510(k) history	1 submissions · 1 cleared · 2014-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)  
 Device record: <https://www.510kdatabase.net/k133527/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).  
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