

**K033630 MODIFICATION OF: SPHERO FLEX, PIVOT FLEX, AND SPHERO BLOCK**

Apr 21, 2004  
156 days to decision

K033630 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k033630/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Nov 17, 2003
Decision date	Apr 21, 2004
Days to decision	156 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Rhein 83 Srl</b>
Location	Hoboken, NJ, US
Contact	JOSEPH E GRASSO
510(k) history	4 submissions · 4 cleared · 2004-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)  
 Device record: <https://www.510kdatabase.net/k033630/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).  
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