

**K090005 BRANEMARK INTEGRATION BIOHELIX IMPLANTS**May 19, 2009  
137 days to decisionK090005 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k090005/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jan 2, 2009
Decision date	May 19, 2009
Days to decision	137 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Branemark Integration AB</b>
Location	Gotborg, SE
Contact	AGNETA SVENSSON
510(k) history	3 submissions · 3 cleared · 2002-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090005/> 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 23, 2026