

# K190662 MRI Compatibility for Existing Straumann Dental Implant Systems

Jun 17, 2019  
94 days to decision

K190662 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k190662/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 15, 2019
Decision date	Jun 17, 2019
Days to decision	94 days
Third-party review	No
Summary / Statement	Statement

## APPLICANT

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Company	<b>Straumann USA, LLC</b>
Location	Andover, MA, US
Contact	Loretta Kushner-Mooney
510(k) history	24 submissions · 24 cleared · 2012-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k190662/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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