

K223697 MRI compatibility for existing BioHorizons dental implants and abutmentsOct 13, 2023
308 days to decisionK223697 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k223697/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 9, 2022
Decision date	Oct 13, 2023
Days to decision	308 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	BioHorizons Implant Systems, Inc.
Location	Birmingham, AL, US
Contact	Paul Leppo
510(k) history	40 submissions · 40 cleared · 1996-2025

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