

K240651 MRI UniversalJul 12, 2024
127 days to decisionK240651 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k240651/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Mar 7, 2024
Decision date	Jul 12, 2024
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Leibinger GmbH & Co KG
Location	Freiburg Im Breisgau, DE
Contact	Amelia Kesti
510(k) history	21 submissions · 21 cleared · 2009-2026

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