

K240262 BTI Interna 3.0 Dental Implant System UnicCa®Oct 10, 2024
253 days to decisionK240262 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k240262/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jan 31, 2024
Decision date	Oct 10, 2024
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	B.T.I. Biotechnology Institute, SI.
Location	01510 Minano (Alava), ES
Contact	José Ramón Rivero
510(k) history	15 submissions · 15 cleared · 2003-2024

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Kevin Thomas

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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