

K011022 BIOUNIVERSAL PDFMay 2, 2001
28 days to decisionK011022 · Product code: **EJT** · DentalSource: <https://www.510kdatabase.net/k011022/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alloy, Gold-based Noble Metal (EJT)
Date received	Apr 4, 2001
Decision date	May 2, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ivoclar North America, Inc.
Location	Amherst, NY, US
Contact	ANDY GULATI
510(k) history	131 submissions · 131 cleared · 1989-2001

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