

K011569 BIOSORBFX O/M 2.0/2/4 SYSTEMFeb 22, 2002
277 days to decisionK011569 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k011569/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	May 21, 2001
Decision date	Feb 22, 2002
Days to decision	277 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionx Implants, Inc.
Location	Tampere, FI
Contact	TUIJA ANNALA
510(k) history	18 submissions · 18 cleared · 1998-2002

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