

K002619 NEWGEN SYSTEMNov 16, 2000
85 days to decisionK002619 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k002619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Aug 23, 2000
Decision date	Nov 16, 2000
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Instruments
Location	Kalamazoo, MI, US
Contact	ROBIN L ROWE
510(k) history	73 submissions · 73 cleared · 1994-2026

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