

**K040650 BONAMATES SERIES**Jun 3, 2004  
84 days to decisionK040650 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k040650/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Mar 11, 2004
Decision date	Jun 3, 2004
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Biotech One, Inc.</b>
Location	Laguna Niguel, CA, US
Contact	KAREN UYESUGI
510(k) history	2 submissions · 2 cleared · 2004-2006

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040650/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 1, 2026