

**K972463 THE BIOPLATE RIGID FIXATION BONE PLATING SYSTEM FOR CRANIOMAXILLOFACIAL SURGERY**Sep 25, 1997  
86 days to decisionK972463 · Product code: JEY · Dental  
Source: <https://www.510kdatabase.net/k972463/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Jul 1, 1997
Decision date	Sep 25, 1997
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Biomedics</b>
Location	Mchenry, IL, US
Contact	CAROL E JONES
510(k) history	10 submissions · 10 cleared · 1980-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972463/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 21, 2026