

**K073006 OSTEOTRANS -MX BIOABSORBABLE BONE  
FIXATION SYSTEM**May 29, 2008  
218 days to decisionK073006 · Product code: **GWO** · Neurology  
Source: <https://www.510kdatabase.net/k073006/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Oct 24, 2007
Decision date	May 29, 2008
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Takiron Co., Ltd.</b>
Location	Himeji, Hyogo, JP
Contact	KUNIHURO HATA
510(k) history	6 submissions · 6 cleared · 2007-2008

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k073006/> Data sourced from FDA 510(k) public records (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 May 19, 2026