

**K001353 MEMOGRAPH**Mar 13, 2001  
319 days to decisionK001353 · Product code: **HBW** · Neurology  
Source: <https://www.510kdatabase.net/k001353/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Plate, Cranioplasty (HBW)
Date received	Apr 28, 2000
Decision date	Mar 13, 2001
Days to decision	319 days
Third-party review	No
Summary / Statement	Summary
Other names	OSSTAPLE - NEUROSURGICAL USES FOR CRANIOFACIAL FRACTURES AND CRANIOPLASTY FOR THE MEMOGRAPH STAPLE SYSTEM

**APPLICANT**

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Company	<b>Biomedical Ent., Inc.</b>
Location	San Antonio, TX, US
Contact	W. CASEY FOX
510(k) history	13 submissions · 13 cleared · 1996-2014

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001353/> 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 May 17, 2026