

**K033230 TRACERS TA BONE CEMENT OPACIFIER, MODEL
TCR-TA**Dec 12, 2003
67 days to decisionK033230 · Product code: **MYU** · Neurology
Source: <https://www.510kdatabase.net/k033230/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accessory, Barium Sulfate, Methyl Methacrylate For Cranioplasty (MYU)
Date received	Oct 6, 2003
Decision date	Dec 12, 2003
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Parallax Medical, Inc.
Location	Scotts Valley, CA, US
Contact	LINDA PAUL
510(k) history	6 submissions · 6 cleared · 1999-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033230/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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