

**K122503 PARALLAX BALLOON INFLATABLE BONE TAMP-10  
MM BALLOON PARALLAX BALLOON INFLATABLE BONE  
TAMP-15 MM BALLOON PARALLAX BALLOON**Jun 25, 2013  
313 days to decisionK122503 · Product code: **NDN** · Orthopedic  
Source: <https://www.510kdatabase.net/k122503/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Aug 16, 2012
Decision date	Jun 25, 2013
Days to decision	313 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Neuro Therm, Inc.</b>
Location	Middleton, MA, US
Contact	F. DAVID ROTHKOPF
510(k) history	3 submissions · 3 cleared · 2006-2013

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122503/> 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 18, 2026