

**K043075 TENACORE TRANSDUCERS FOR FETAL  
ULTRASONIC AND TOKODYNAMOMETER MONITORING**Aug 18, 2005  
283 days to decisionK043075 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k043075/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Nov 8, 2004
Decision date	Aug 18, 2005
Days to decision	283 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Tenacore Holdings, Inc.</b>
Location	Mission Viejo,, CA, US
Contact	Brand Caso
510(k) history	4 submissions · 4 cleared · 2002-2008

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043075/> 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. - Generated May 24, 2026