

**K043354 MODULAR TELEMETRY SYSTEM FOR THE VISION
TELEPAK, MODEL 20701**Jan 10, 2005
35 days to decisionK043354 · Product code: DRT · Cardiovascular
Source: <https://www.510kdatabase.net/k043354/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Dec 6, 2004
Decision date	Jan 10, 2005
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Invivo Research, Inc.
Location	Orlando, FL, US
Contact	NEIL BATTISTE
510(k) history	14 submissions · 14 cleared · 1989-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043354/> 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 27, 2026