

**K122897 SENSE HEAD 16 MODEL 800647, SENSE SPINE 16
MODEL 800646**Dec 21, 2012
91 days to decisionK122897 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k122897/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Sep 21, 2012
Decision date	Dec 21, 2012
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary
Other names	SENSE TORSO 16 MODEL 800645

APPLICANT

Company	Invivo Corporation
Location	Pewaukee, WI, US
Contact	LANCE AULABAUGH
510(k) history	29 submissions · 29 cleared · 2005-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122897/> 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 17, 2026