

**K132444 ATAMA SYSTEM**Jan 27, 2014  
174 days to decisionK132444 · Product code: **MOS** · Radiology  
Source: <https://www.510kdatabase.net/k132444/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Aug 6, 2013
Decision date	Jan 27, 2014
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Monteris Medical,</b>
Location	Alameda, CA, US
Contact	BRIAN J EDWARDS
Website	<a href="https://www.monteris.com">https://www.monteris.com</a>
510(k) history	12 submissions · 12 cleared · 2009-2026

Monteris Medical is a leader in minimally invasive laser ablation technology for the brain. The company develops and markets the NeuroBlate® System, a robotic, MR-guided laser interstitial thermal therapy (LITT) platform designed for neurosurgical applications. Monteris operates with a manufacturing facility in Alameda, US. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2009. Monteris specializes in neurology devices, with a focus on thermal ablation systems for brain tumors, radiation necrosis, and drug-resistant epilep...

---