

**K090240 MONTERIS MEDICAL UFO**Aug 6, 2009  
185 days to decisionK090240 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k090240/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Feb 2, 2009
Decision date	Aug 6, 2009
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Monteris Medical,</b>
Location	Alameda, CA, US
Contact	CRAIG COOMBS
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...

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