

**K171309 BR-FHUS Navigation 1.0**Sep 29, 2017  
149 days to decisionK171309 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k171309/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	May 3, 2017
Decision date	Sep 29, 2017
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Taihao Medical, Inc.</b>
Location	Taipei, TW
Contact	Hsin Hung Lai
510(k) history	4 submissions · 4 cleared · 2016-2021

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171309/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026