

**K163037 Intra medullary endo-transilluminating device (iMET device)**Feb 17, 2017  
109 days to decisionK163037 · Product code: **HRX** · Orthopedic  
Source: <https://www.510kdatabase.net/k163037/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Oct 31, 2016
Decision date	Feb 17, 2017
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>WeMED Bio-Tech, Inc.</b>
Location	Taipei City, TW
Contact	YIN-JIUN TSENG
510(k) history	1 submissions · 1 cleared · 2017-2017

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163037/>. 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 16, 2026