

**K013722 MODIFICATION TO: EUB-8500 DIAGNOSTIC  
ULTRASOUND SCANNER**Feb 11, 2002  
94 days to decisionK013722 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k013722/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 9, 2001
Decision date	Feb 11, 2002
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Hitachi Medical Corp.</b>
Location	Tokyo, JP
Contact	WALTER WEYBURNE
510(k) history	11 submissions · 11 cleared · 1982-2008

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013722/> 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 18, 2026