

K890802 COTUBE(TM) TSH IRMAMar 28, 1989
40 days to decisionK890802 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k890802/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Feb 16, 1989
Decision date	Mar 28, 1989
Days to decision	40 days
Third-party review	No

APPLICANT

Company	Bio-Rad
Location	Mchenry, IL, US
Contact	LYNN C SHANTA
Website	http://www.bio-rad.com
510(k) history	319 submissions · 319 cleared · 1976-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k890802/> 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 14, 2026