FDA 510(k) Premarket Notification

K930010 ACCESS THYROID UPTAKE ASSAY

CLEARED

Jun 7, 1993
154 days to decision

K930010 · Product code: **CEE** · Chemistry
Source: https://www.510kdatabase.net/k930010/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroxine-binding Globulin (CEE)
Date received	Jan 4, 1993
Decision date	Jun 7, 1993
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Rad Laboratories, Inc.**
Location	Chaska, MN, US
Contact	JAN OLSEN
Website	http://www.bio-rad.com
510(k) history	82 submissions · 82 cleared · 1991-2019

Bio-Rad Laboratories, Inc. is an American developer and manufacturer of specialized technological products for life science research and clinical diagnostics. Founded in 1952 in Berkeley, California, the company is based in Hercules, California, with operations worldwide. Bio-Rad has received FDA 510(k) clearances from total submissions between 1991 and 2019. The company's regulatory record reflects a strong focus on chemistry devices, including hemoglobin testing systems, quality control materials, and diagnostic assays. Additional cleared devices span immunology, hemato...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k930010/ 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 June 18, 2026