FDA 510(k) Premarket Notification

K960412 T-3 MICROWELL EIA MODEL 7013

CLEARED

Mar 19, 1996
50 days to decision

K960412 · Product code: **CDP** · Chemistry
Source: https://www.510kdatabase.net/k960412/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Total Triiodothyronine (CDP)
Date received	Jan 29, 1996
Decision date	Mar 19, 1996
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomerica, Inc.**
Location	Newport Beach, CA, US
Contact	JOSEPH IRANI
Website	http://www.biomerica.com
510(k) history	10 submissions · 10 cleared · 1991-2023

Biomerica, Inc. is a global biomedical technology company developing, manufacturing, and marketing advanced in-vitro diagnostic products. Headquartered in Irvine, California, the company operates FDA and CE registered manufacturing facilities in California and Mexico, specializing in gastrointestinal and inflammatory disease diagnostics. Biomerica has received FDA 510(k) clearances from total submissions since 1991. The company's cleared devices span chemistry, microbiology, and immunology categories, including pregnancy tests, thyroid function assays, H. pylori detection...