FDA 510(k) Premarket Notification

K950588 T4 MICROWELL EIA (ENZYME IMMUNOASSAY0

CLEARED

Jun 29, 1995
140 days to decision

K950588 · Product code: **KLI** · Chemistry
Source: https://www.510kdatabase.net/k950588/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI)
Date received	Feb 9, 1995
Decision date	Jun 29, 1995
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Biomerica, Inc.**
Location	Newport Beach, CA, US
Contact	PERRY G RUCKER
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...