

K982954 FREE T4 MICROWELL EIA, MODEL #7019Sep 24, 1998
31 days to decisionK982954 · Product code: **CEC** · Chemistry
Source: <https://www.510kdatabase.net/k982954/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Free Thyroxine (CEC)
Date received	Aug 24, 1998
Decision date	Sep 24, 1998
Days to decision	31 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Biomerica, Inc.
Location	Newport Beach, CA, US
Contact	JAY SINGH
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...
