FDA 510(k) Premarket Notification

K970353 AURA TEK FDP

CLEARED

Apr 30, 1997
90 days to decision

K970353 · Product code: **MMW** · Immunology
Source: https://www.510kdatabase.net/k970353/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Tumor Marker, Monitoring, Bladder (MMW)
Date received	Jan 30, 1997
Decision date	Apr 30, 1997
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Perimmune, Inc.**
Location	Rockville, MD, US
Contact	SHERYL RUPPEL
510(k) history	2 submissions · 2 cleared · 1997-1997