

K970353 AURA TEK FDPApr 30, 1997
90 days to decisionK970353 · 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

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