FDA 510(k) Premarket Notification

K972093 REGENESIS MODEL 42

CLEARED

Oct 21, 1997
139 days to decision

K972093 · Product code: **ILX** · Physical Medicine
Source: https://www.510kdatabase.net/k972093/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diathermy, Shortwave, For Use Other Than Applying Therapeutic Deep Heat (ILX)
Date received	Jun 4, 1997
Decision date	Oct 21, 1997
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Regenesis Biomedical, Inc.**
Location	Scottsdale, AZ, US
Contact	T. WHIT ATHEY
510(k) history	4 submissions · 4 cleared · 1997-2023