FDA 510(k) Premarket Notification

K000870 KM-10 TENS ELECTRODE

CLEARED

Nov 7, 2000
232 days to decision

K000870 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k000870/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Mar 20, 2000
Decision date	Nov 7, 2000
Days to decision	232 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Katecho, Inc.**
Location	Des Moines, IA, US
Contact	WARREN R WALTERS
510(k) history	26 submissions · 25 cleared · 1984-2001