FDA 510(k) Premarket Notification

K001347 MERIDIAN-II AND MERDIAN-PLUS

CLEARED

Nov 3, 2000
189 days to decision

K001347 · Product code: **GZO** · Neurology
Source: https://www.510kdatabase.net/k001347/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Galvanic Skin Response Measurement (GZO)
Date received	Apr 28, 2000
Decision date	Nov 3, 2000
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Meridian Co., Ltd.**
Location	Songpa-Gu, Seoul, KR
Contact	SOO-RANG LEE
510(k) history	7 submissions · 7 cleared · 2000-2011