FDA 510(k) Premarket Notification

K001980 ASPECT MEDICAL SYSTEMS PEDIATRIC BIS EEG SENSOR, MODEL 186-0110

CLEARED

Sep 27, 2000
90 days to decision

K001980 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k001980/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Jun 29, 2000
Decision date	Sep 27, 2000
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aspect Medical Systems, Inc.**
Location	Framingham, MA, US
Contact	CHRISTINE M VOZELLA
510(k) history	25 submissions · 25 cleared · 1992-2009

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k001980/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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