FDA 510(k) Premarket Notification

K790011 STIMULATOR, MENTOR 100 NERVE

CLEARED

Mar 2, 1979
59 days to decision

K790011 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k790011/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Jan 2, 1979
Decision date	Mar 2, 1979
Days to decision	59 days
Third-party review	No

APPLICANT

Company	**Mentor Corp.**
Location	Mchenry, IL, US
510(k) history	61 submissions · 61 cleared · 1977-2013

Mentor Corp. is a surgical aesthetics and medical device company based in McHenry, US. Now part of Johnson & Johnson MedTech, the brand supplies products to plastic surgeons and specialists worldwide. Mentor has received FDA 510(k) clearances from total submissions since its first clearance in 1977. The company's regulatory record spans General & Plastic Surgery, Gastroenterology & Urology, Obstetrics & Gynecology, and Radiology device categories. The latest clearance was recorded in 2013, reflecting the company's historical significance in surgical device innovation. Men...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k790011/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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