FDA 510(k) Premarket Notification

K220920 Matreneu Percutaneous Balloon Compression Kit

CLEARED

Sep 7, 2022
161 days to decision

K220920 · Product code: **HAO** · Neurology
Source: https://www.510kdatabase.net/k220920/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Surgical, Non-powered (HAO)
Date received	Mar 30, 2022
Decision date	Sep 7, 2022
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Shineyard Medical Device Co. , Ltd.**
Location	Shenzhen, CN
Contact	Yan Ping
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Joyantech Consulting Co., Ltd.**
Contact	Joyce Yang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov