FDA 510(k) Premarket Notification

CLEARED

K141869 QFLOW 500 TITANIUM BOLT, QUAD LUMEN BOLT KIT

Oct 10, 2014
91 days to decision

K141869 · Product code: **GWM** · Neurology
Source: https://www.510kdatabase.net/k141869/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Monitoring, Intracranial Pressure (GWM)
Date received	Jul 11, 2014
Decision date	Oct 10, 2014
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hemedex Incorporated**
Location	Hopkonton, MA, US
Contact	DEAN HONKONEN
510(k) history	4 submissions · 4 cleared · 2002-2014