FDA 510(k) Premarket Notification

CLEARED

K172035 EKOS ultrasound EVD Device, EVD Control Unit

Mar 24, 2018
262 days to decision

K172035 · Product code: **JXG** · Neurology
Source: https://www.510kdatabase.net/k172035/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Jul 5, 2017
Decision date	Mar 24, 2018
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Btg International, Inc.**
Location	Bothell, WA, US
Contact	Brit Baird
510(k) history	6 submissions · 6 cleared · 2014-2019

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k172035/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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