

K192834 MECTA SigmaApr 26, 2020
207 days to decisionK192834 · Product code: **QGH** · Neurology
Source: <https://www.510kdatabase.net/k192834/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electroconvulsive Therapy Device For Catatonia, Major Depressive Disorder, And Bipolar Disorder (QGH)
Date received	Oct 2, 2019
Decision date	Apr 26, 2020
Days to decision	207 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Mecta Corporation
Location	Suite B, OR, US
Contact	Robin Nicol
510(k) history	2 submissions · 2 cleared · 2020-2021

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