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Device Classification Name	Full-Montage Standard Electroencephalograph ²³²²
510(k) Number	K193159
Device Name	NeuroAmp II, NeuroAmp II.5s
Applicant	Corscience GmbH & Co. KG Hartmannstrasse 65 Erlangen, DE 91052
Applicant Contact	Stefan Bolleining
Correspondent	Corscience GmbH & Co. KG Hartmannstrasse 65 Erlangen, DE 91052
Correspondent Contact	Stefan Bolleining
Regulation Number	882.1400 ²⁴²³
Classification Product Code	GWQ ²⁵²⁴
Subsequent Product Codes	GWE ²⁶²⁵ GWJ ²⁷²⁶ HCC ²⁸²⁷ OLV ²⁹²⁸
Date Received	11/15/2019
Decision Date	12/30/2020
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Neurology
510k Review Panel	Neurology
Summary	Summary ³⁰²⁹
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

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