

K253256 myosmart. (13E522)Apr 22, 2026
205 days to decisionK253256 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k253256/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Sep 29, 2025
Decision date	Apr 22, 2026
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	myosmart.cuff (757M20-2); connectgrip. (560X27-1); myosmart trial kit (642V64=T)

APPLICANT

Company	Otto Bock Healthcare Products GmbH
Location	Vienna, AT
Contact	Reinhard Wolkerstorfer
510(k) history	3 submissions · 3 cleared · 2015-2026

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