FDA Executive Summary

Prepared for the **Spring 2026 Review** by the FDA's Pediatric Advisory Committee

Medtronic Activa Dystonia Therapy (H020007)

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I. INTRODUCTION

In accordance with the Pediatric Medical Device Safety and Improvement Act, this review provides a safety update based on the post-market experience with the use of the Medtronic Activa Dystonia Therapy in pediatric patients since approval in 2003 under Humanitarian Device Exemption (HDE) H020007. The purpose of this review is to provide the Pediatric Advisory Committee (PAC) with post-market safety data so the committee can advise the Food and Drug Administration (FDA) on whether they have any new safety concerns and whether they believe that the HDE remains appropriately approved for pediatric use.

This memorandum summarizes the safety data regarding H020007 for the current review period including pre-market clinical data, post-market medical device reporting (MDR) for adverse events, and peer-reviewed literature regarding safety data associated with the device.

II. INDICATIONS FOR USE

The Medtronic Activa Dystonia Therapy is indicated for unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) to aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis) in patients seven years of age or above.

Modifications from the Humanitarian Use Device (HUD) Designation: None

III. BRIEF DEVICE DESCRIPTION

The Medtronic Activa Dystonia Therapy is a deep brain stimulation system intended for treatment of chronic, intractable primary dystonia in pediatric patients. The system provides electrical stimulation to targeted brain regions to manage dystonia symptoms.

The Medtronic Activa Dystonia Therapy Kits are composed of the neurostimulator, extension, and lead for implantation of the entire system. The system also includes instrumentation for implantation, programming, and a controller for device management. The system utilizes devices approved under HDE H020007 (Medtronic Activa Dystonia Therapy) and identical devices approved under premarket approval (PMA) P960009 (Medtronic Activa Tremor Control System) indicated for patients with movement disorders and epilepsy. Patients implanted with the PMA approved device that is being used for the HDE-approved dystonia indication are also provided with the device manual(s) and labeling information associated with the dystonia indication for use.

IV. REGULATORY HISTORY AND CURRENT STATUS

The Medtronic Activa Dystonia Therapy received HUD designation on November 27, 2001. The HDE was approved on April 15, 2003, by the Center for Devices and Radiological Health (CDRH) of the FDA.

Annual reports have been consistently submitted by the firm and reviewed and accepted by FDA. At this time, in review of the data relating to safety and probable benefit, FDA believes the HDE remains appropriately approved for pediatric use.

V. ANNUAL DISTRIBUTION NUMBER (ADN) AND UNITED STATES (US) DEVICE DISTRIBUTION DATA

Section 520(m)(6)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) allows HDEs indicated for pediatric use to be sold for profit as long as the number of devices distributed in any calendar year does not exceed the annual distribution number (ADN). On December 13, 2016, the 21st Century Cures Act (Pub. L. No. 114-255) updated the definition of ADN to be the number of devices "reasonably needed to treat, diagnose, or cure a population of 8,000 individuals in the United States." Based on this definition, FDA calculates the ADN to be 8,000 multiplied by the number of devices reasonably necessary to treat an individual.

The number of Medtronic Activa Dystonia Therapy Kits sold provides a reasonable representation of the number of individuals treated with the device. There were zero (0) Medtronic Activa Dystonia Therapy Kits sold in the US in the year 2025 (see below). The ADN of 8,000 has not been exceeded in 2025.

Medtronic Activa Dystonia Therapy Kit Number	Neurostimulator Kit Model Name	Number of Kits Sold
3307*	*Soletra Model 7426****	0
3309*	*Soletra Model 7426****	0
3310**	*Activa PC Model 37601****	0
3317*	*Activa PC Model 37601****	0
3319*	*Activa PC Model 37601****	0
3320**	*Activa SC Model 37602*	0
3330**	Activa SC Model 37603	0
3337*	Activa SC Model 37603	0
3339*	Activa SC Model 37603	0
33TH17*	*Activa PC Model 37601****	0
33TH19*	*Activa PC Model 37601****	0
33TH37*	Activa SC Model 37603	0
33TH39*	Activa SC Model 37603	0
33TH40**	Percept PC Model B35200	0
33TH47*	Percept PC Model B35200	0
33TH49*	Percept PC Model B35200	0
33TH60**	Percept RC Model B35300	0
33TH57	Percept PC Model B35200	0
33TH59	Percept PC Model B35200	0
33TH67	Percept RC Model B35300	0
33TH69	Percept RC Model B35300	0

Total		**0**

Data timeframe: January 1, 2025 - December 31, 2025.
*Kits discontinued.
**Kits provided for replacement procedures when only the neurostimulator needs to be replaced (e.g., following normal device battery depletion).
****Medtronic no longer manufactures the Soletra Model 7426, Activa PC Model 37601, and Activa SC Model 37602.*
Note: There were no (0) HDE kit sales due to all 2025 implants being PMA cleared device kits

Number of Dystonia Devices Implanted and Active Implants (In Use) in the Calendar Year 2025	
# Devices Implanted	10,378
# Active Implants	64,042
# Implants in Pediatric Patients in the Year	259
# Active Implants in Pediatric Patients in the Year	1,136

Data timeframe: January 1, 2025 - December 31, 2025.
*Implanted and active devices include the following device components: neurostimulator(s), leads, and extensions.
Note: All 2025 implants were PMA cleared device kits

VI. POST-MARKET CLINICAL EXPERIENCE

A. Post-Approval Study (PAS) Status

No post-approval study was required for this device.

B. Sponsor Annual Reports

The sponsor continues to submit annual reports documenting device distribution and safety data. No new safety concerns have been identified through sponsor reporting.

VII. ADVERSE EVENTS AND SAFETY DATA

A. Overview of the MDR Database

The FDA's MDR database receives over 2 million reports annually documenting suspected device-associated deaths, serious injuries, and malfunctions. The database collects reports from both mandatory sources (manufacturers, importers, device user facilities) and voluntary sources (healthcare professionals, patients, consumers).

Primary Uses of MDR Data:
Monitor device performance and detect potential safety issues in real-world settings.
Provide qualitative snapshots of adverse events for specific devices or device types.
Identify various types of problems including rare or unexpected events, long-term use complications, issues affecting vulnerable populations, and use errors.

Key Limitations of the MDR System:

- Cannot be used to establish, evaluate, or compare rates.

- Reports may be incomplete, inaccurate, untimely, unverified, or biased.

MDR data does not represent all known safety information for a reported medical device and should be interpreted in the context of other available information when making device-related or treatment decisions. More information about MDRs and how to access MDR data is available at Medical Device Reporting (MDR): How to Report Medical Device Problems | FDA.

B. Known Adverse Events

Adverse events associated with the Medtronic Activa Dystonia Therapy are well-established from clinical experience and include events related to the surgical procedure, device components, and stimulation therapy. Known adverse events include infection, lead fractures, hardware breakage, device explant/replacement, battery/charging issues, and return or worsening of dystonia symptoms.

C. MDRs

Search Methodology: FDA's internal MDR database was searched on November 20, 2025, utilizing the following criteria:

- Product codes: MRU, MHY, PJS.
- Reports entered dates between September 28, 2024, and September 27, 2025.

The search resulted in the identification of 273 MDRs associated with Medtronic Activa Dystonia Therapy which were all submitted by the manufacturer. These MDRs were cross checked with the manufacturer adverse event database to ensure accuracy. The reports entered during this timeframe are related to devices reported to be implanted between March 26, 2009, and July 24, 2025. 214 MDRs originated in the United States, 53 originated outside the United States, and 6 MDRs did not report the country of origin. Patient sex was reported in 246 of the MDRs, of which 137 were female and 109 were male patients. Patient age was available in 189 MDRs, which included 21 pediatric reports and 168 adult reports. The patient age was not reported in 84 reports.

D. Pediatric MDR Review (n= 21):

The reporting country for the majority of pediatric MDRs was the United States (n= 17 MDRs); 3 MDRs were reported from outside the United States, and 1 MDR did not report a country of origin. Within the pediatric reports, 8 MDRs were associated with female patients, 12 MDRs were associated with male patients, and 1 MDR reported “Unknown” patient sex. Pediatric patient age ranged from 7 years of age to 21.8 years of age. The average age of the patients in the pediatric reports was 15.6 years of age.

The time-to-event (TTE) for the pediatric MDRs was calculated based on the reported implant date and date of event provided for each MDR. TTE was calculable for 17 of the 21 pediatric reports received. The remaining 4 MDRs did not report an implant date or erroneously reported an implant date prior to the date of event; therefore, TTE was not calculable. The range of TTE was from 0 (day of implant) to 2753 days (7.5 years) with an average of 1002 days (2.7 years) and median of 1009 days (2.8 years).

All pediatric reports were individually reviewed to identify new events and events that were previously determined to be clinically significant or concerning by CDRH clinicians

with input from previous PAC panel members, and to be consistent with prior MDR analyses. There were no new/previously unknown adverse events reported.

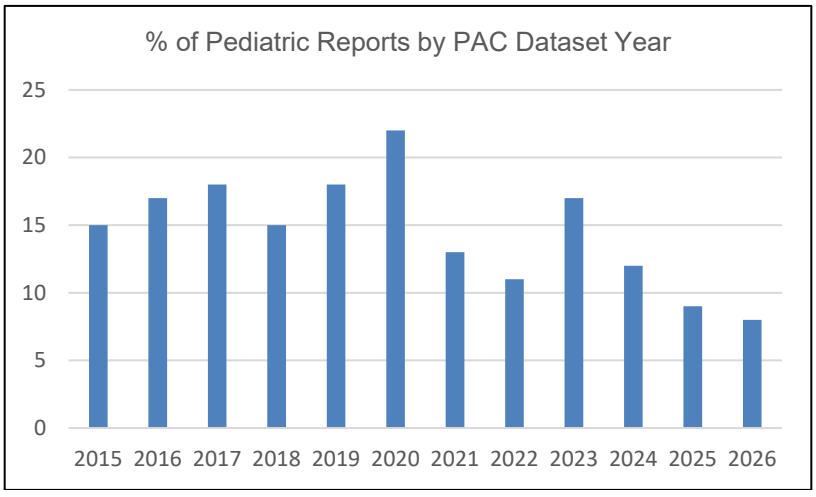
Summary of Pediatric MDRs Table

Adverse Event	*MDR Report Count	Number of Unique Events	Injury Event Type	Malfunction Event Type
Battery/charging issue	9	8	0	9
Device explanted	5	5	5	0
Impedance issue	4	4	3	1
Device replaced	3	3	3	0
Device settings/programming issue	3	3	0	3
Lead break/fracture	2	2	2	0
Ineffective therapy	2	2	1	1
Migration or erosion	2	2	2	0
Return or worsening of symptoms	1	1	0	1
Electromagnetic interference (EMI)	1	1	0	1
Discomfort	1	1	1	0
Seizure	1	1	1	0
TOTAL	34	33	18	16

* A single MDR may be associated with more than one type of adverse event.

Of note, the percentages of pediatric reports within PAC data sets reviewed annually between the 2015 and 2026 data sets ranged from 8% and 22%. The lowest percentage of pediatric age reports were in the 2026 data set (see Chart 1).

Chart 1. Percentage of Pediatric Reports by PAC Data Set Year



Key Findings:

- No new patient or device problems were identified in the 2026 PAC data.
- No MDRs associated with pediatric death were reported.
- Battery/charging issues (n= 9) were the most frequently reported device problem.
- Device explant (n= 5) was the most frequently reported patient problem and were

associated with impedance issues, broken lead or extension, and erosion of the implantable pulse generator (IPG).
- All reported problems are consistent with known risks documented in device labeling and literature associated with the device.

E. Literature Review

Purpose: The objective of this systematic literature review (SLR) is to provide an update of post-market safety/adverse events (AEs) associated with the use of the Medtronic Activa Dystonia Therapy. This is an update on the systematic assessment of published literature since the 2025 PAC data set.

Specifically, the systematic review was conducted to address the following question:

What is the safety of the Medtronic Activa Dystonia Therapy for the treatment of dystonia in the pediatric population?

Methods: A literature search was conducted by FDA using similar search criteria applied in previous presentations to the PAC:

(medtronic dystonia) OR (medtronic activa deep brain stimulation) OR (medtronic dbs) OR (medtronic activa) OR (activa) OR (soletra) OR (percept) OR (dbs) AND (pediatric) AND (Dystonia).

The search was conducted on November 20, 2025, using two electronic biomedical databases (PubMed and Embase) for the period between November 7, 2024, and November 6, 2025 (dates included). The following inclusion and exclusion criteria were used:

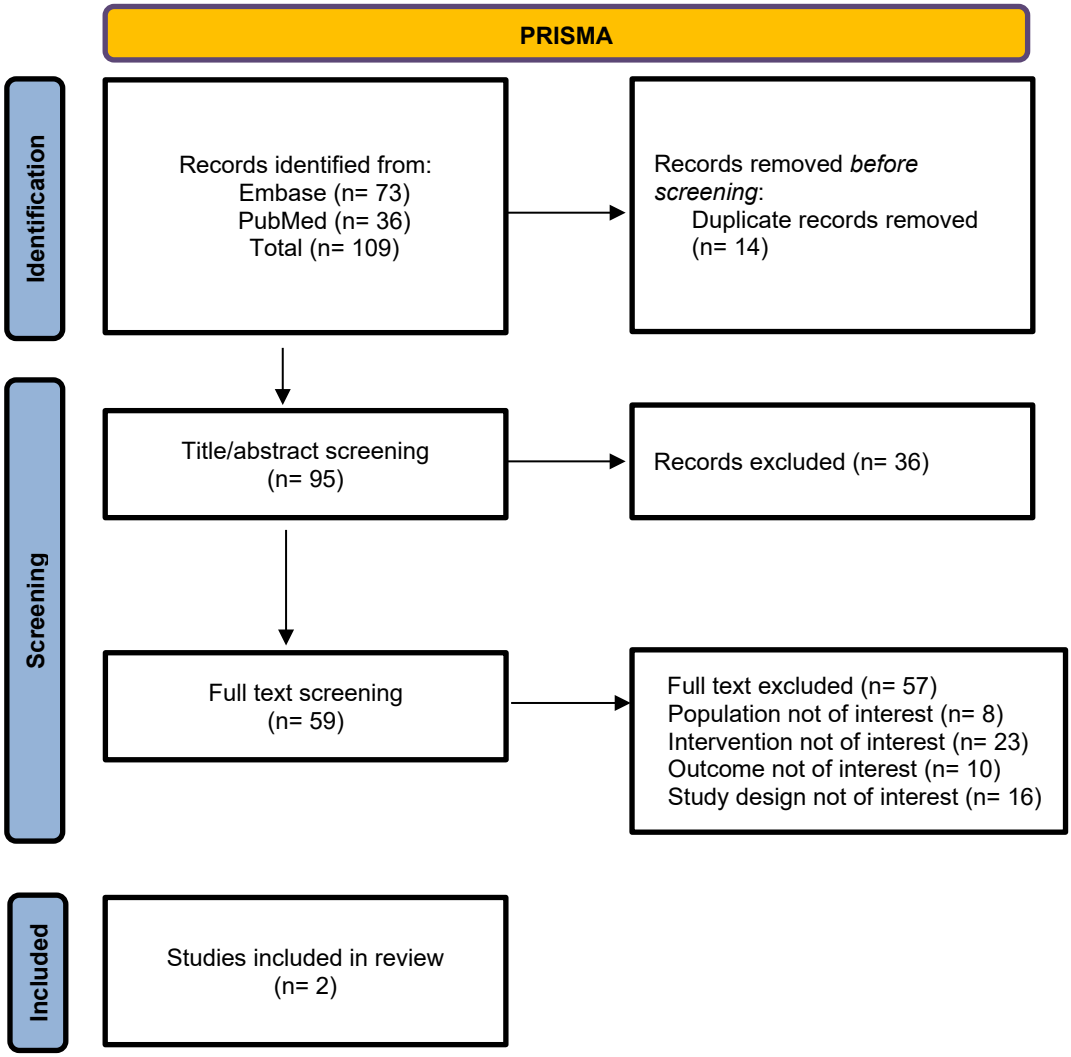
PICOTS (Population, Intervention, Comparison, Outcomes, Timing and Setting)	Inclusion Criteria	Exclusion Criteria
Population	Children from birth to < 22 years of age with chronic, intractable primary dystonia, including focal, segmental, generalized, or hemidystonia.	Non-pediatric or combined (pediatric and adult) population where pediatric and adult subjects are not analyzed separately. Not a primary dystonia (secondary or acquired).
Intervention	Medtronic Activa Dystonia Therapy system (both on- and off-label use, with off-label use targeting other than STN and GPi).	No use of Medtronic device or unknown device.
Comparison	• Other active treatments or standard of care (e.g., botulinum toxic injections, medications, occupational/physical therapy, speech therapy, surgery). • No comparison group.	No exclusion.

PICOTS (Population, Intervention, Comparison, Outcomes, Timing and Setting)	Inclusion Criteria	Exclusion Criteria
Outcomes	Safety 1. New safety concerns not listed at time of HDE approval. 2. Known/anticipated safety concerns: a. Hemiplegia/hemiparesis b. Worsening of motor impairment (e.g., gait impairment and falls) c. Dysphagia d. Sensory impairment e. Speech/language f. Subcutaneous hemorrhage/seroma g. Cerebral spinal fluid abnormality h. Seizures i. General* i. Infection ii. Erosion iii. Lead fractures iv. Hardware breakage v. IPG failure j. Déjà vu corrected by surgically revised lead placement k. Irritating cough with stimulation ON 3. Other AEs, e.g., those similar to AEs recorded with Activa systems approved for Parkinson's disease and Essential Tremor (see appendix). *Includes adverse events related to the system components.	Studies will be excluded if they do not report safety outcomes.
Timing	Any	No exclusion.
Setting	US and Outside the US (OUS)	No exclusion.
Study Design	• Randomized controlled trials (RCTs) • Cohort studies (prospective/retrospective) • Case-control studies • Cross-sectional studies • Case series • Case reports • Systematic literature reviews (SLRs) • Meta-analyses (MAs)	• Laboratory studies • Animal studies • Narrative review articles • Registries • Unavailable articles • SLRs and MAs for which all included references were published prior to November 6, 2024 • Registries • Duplicates and corrections/errata • Conference abstracts/oral presentations
Language	Articles published in English.	Non-English language articles.

PICOTS (Population, Intervention, Comparison, Outcomes, Timing and Setting)	Inclusion Criteria	Exclusion Criteria
Publication Dates	November 7, 2024, to November 6, 2025	Published outside of date range.

Search Outcome: 109 records were identified from database searches, and after de-duplication, 95 unique records were screened for eligibility, and 36 were excluded at the title and abstract level because they were irrelevant to this review. Of the 59 records retrieved and screened in full-text, 57 studies were excluded because the intervention was not of interest (no use of Medtronic device or unknown device use)(n = 23), the study design was not of interest (n = 16), the population was not of interest (n = 8), or the outcome was not of interest (n = 10). The SLR identified two (2) primary studies for inclusion in this review. Figure 1 illustrates the PRISMA diagram of the literature flow.

Figure 1. Literature Flow



Results: This SLR yielded two primary studies, both case series, that were deemed relevant based on the established inclusion and exclusion criteria. Of these studies, one was conducted within the United States (US), and one was conducted outside of the US (OUS), including patients from centers located in France, Germany, Italy, the Netherlands, Slovakia, and the United Kingdom.[4,5]

The included studies have important limitations as well as methodological and quality considerations. Both included studies had small sample sizes. The reporting of individual patient-level data allowed for the determination of specific subsets of patients that met the eligibility criteria for this SLR, yielding the small eligible sample size of five patients for the OUS study and two patients for the US study.[4,5] As such, the generalizability of the findings of these studies to broader populations is limited. Second, both studies reported the occurrence of AEs (presence or absence) but did not report the severity of AEs or whether a patient's course of treatment changed because of these AEs. Additionally, the studies did not report how these AEs were validated. Finally, while both

studies were largely funded by research grants, the authors of the OUS study, Svorenova, et al. (2025), reported numerous important conflicts of interest with the device manufacturer, Medtronic, and other similar device manufacturers, including Boston Scientific and Abbott.[4] These conflicts of interest included speaker's honoraria, advisory honoraria, and consultation fees from the device manufacturers.[4] The US study, Liker, et al. (2024), reported no conflicts of interest. Characteristics and outcomes of the included studies are in Appendix A, "Evidence Table."

No studies were identified that reported new safety concerns compared to those that were known or anticipated. No new conclusions regarding the safety of these devices in pediatric populations with primary dystonia can be drawn at this time based on the available literature.

1. **The OUS Study - Svorenova et al. (2025)** [4]

This study reported device and hardware-related complications and stimulation-related side effects at one to three months, six months, twelve months, and last follow-up. At one to three months' follow-up, one patient experienced a device or hardware-related complication ("transient swelling around IPG") and one patient experienced a stimulation-related side effect ("weird sensations in the mouth and tongue").[4] At six months' follow-up, two patients experienced stimulation-related side effects ("articulation and piano play worsened" and "right facial pulling").[4] At twelve months' follow-up, one patient experienced a device or hardware-related complication ("high impedances on not active contact point").[4] No patient experienced a device or hardware-related complication or a stimulation-related complication at last follow-up.[4]

The study consisted of 26 patients, of which data from five patients were relevant to this SLR due to these patients meeting age and intervention criteria.[4] This study provided individual patient-level data, which allowed for the extraction of demographic and outcomes data for this subset of patients. Of these five eligible patients, the mean age was 17.4 years (range 11 to 20 years) and disease duration was 7.2 years (range 3 to 11 years) at deep brain stimulation (DBS) pulse generator implantation.[4] Of these five patients, 20% (n = 1) was female and 100% (n = 5) had Vacuolar Protein Sorting-Associated Protein 16 gene (VPS16 gene) -related primary dystonia.[4] Four of the five patients (80%) received the Medtronic Activa RC device, and one patient received the Medtronic Activa PC device (PMA cleared devices identical to devices approved under the HDE) .[4] Race and ethnicity of participants were not reported. Mean follow-up was 82 months (range 48 to 120 months) after DBS pulse generator implantation.[4]

2. **The US Study - Liker et al. (2024)** [5]

This study reported outcomes of a novel personalized surgical targeting procedure, Stereotactic Awake Basal Ganglia Electrophysiological Recording and Stimulation, which involved multiple phases. The procedure used 4 to 12 temporary electrodes to determine potential neurostimulation sites (phase 1). Following temporary electrode placement, patients were observed for at least five days in a neuromodulation monitoring unit using both stimulation and recording to identify the most appropriate sites for permanent lead

implantation (phase 2). A subset of patients underwent DBS pulse generator implantation (phase 3).

The study consisted of 30 patients, of which data from two patients were relevant to this SLR.[5] Demographic information was reported in aggregate for the full study population, and details were not available specific to the two patients with primary dystonia. The mean age of the entire study population was 13.5 years (range 5 to 20 years) at the time of initial electrode placement, and 43.3% (n = 13) of the study population was female.[5] All patients who progressed to the pulse generator implantation phase of the study (phase 3; n = 26) received the Medtronic Activa RC device, including the two patients with primary dystonia.[5] Race and ethnicity of participants and disease duration at time of DBS pulse generator implantation were not reported. The study follow-up period was three to six months post-operative.[5]

This study reported limited information on AEs, only noting that "no significant adverse events attributable to the staged surgical procedure or observation in the neuromodulation monitoring unit occurred" during the study period.[5]

VIII. SAFETY ASSESSMENT

Evaluation of data available to CDRH, including MDR analysis and literature review, has not identified new safety issues compared to what was known and anticipated at the time of HDE approval in 2003.

The types of adverse events documented in post-market surveillance are consistent with the known safety profile established during clinical studies and documented in device labeling. The most frequently reported events (battery/charging issues and device explant) are known complications associated with neurostimulator devices.

IX. SUMMARY AND RECOMMENDATIONS

Based on the available data, and considering the probable benefits and risks, FDA concludes that the HDE remains appropriately approved for pediatric use. FDA will continue routine surveillance including MDR and literature reviews. FDA will provide focused updated safety and use data to the PAC in 2027. FDA recommends continued surveillance and will report the following to the PAC in 2027:

- Annual Distribution Number
- Post-Market Clinical Experience
- Adverse Event and Safety Data

X. REFERENCES

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Link: https://doi.org/10.1177/08830738231224057

Appendix A. Evidence Table

Study Details	Patients	Study Characteristics	Outcomes Assessed
Reference: Svorenova et al., 2025[4] **Country:** OUS (10 centers in 6 European countries: France, Germany, Italy, the Netherlands, Slovakia, and the UK) **Study Design:** Retrospective case series **Purpose:** To evaluate the effects of DBS in an international cohort of patients with *VPS16*-related dystonia **Funding:** Multiple research grants (e.g., Slovak Grant and Development Agency, EU Recovery and Resilience Plan, Czech Ministry of Health). **COI:** MTB received speaker's honoraria from DBS manufacturers Medtronic, Boston Scientific, Abbott (formerly St. Jude) and advisory honoraria and research funding from Medtronic and Boston Scientific. MS received speaker's honoraria and consultation fees from Medtronic. All other authors declared no COI.	**Sample size:** 26 total patients, of which 5 were eligible for this SLR due to age (< 22 years). *Study provides individual patient-level data. The tabled data pertains to the 5 eligible patients only. **Mean age (range):** 17.4 (11, 20) years at DBS implantation **Sex, N (%):** Female: 1 (20) Male: 4 (80) **Race/ethnicity, N (%):** NR **Mean disease duration at DBS implantation (range):** 7.2 (3, 11) years **Diagnosis, N (%):** *VPS16*-related primary dystonia: 5 (100) **Inclusion criteria:** Patients with genetically confirmed DYT-*VPS16* dystonia treated with implanted DBS with at least one available FU more than one month after DBS surgery and BFMDRS motor sub-score available at least at baseline before surgery and at last FU. **Exclusion criteria:** NR	**Intervention, N (%):** Medtronic Activa RC: 4 (80) Medtronic Activa PC: 1 (20) **Comparator:** None **Mean FU period (range):** 82 (48, 120) months since DBS implantation	**Device/hardware related complications, N (%):** 1-3 months: All 5 patients had data at this time point; 1 of 5 patients (20%) experienced 1 AE: "transient swelling around IPG" 6 months: 3 of 5 patients had data at this time point; 0 of 3 patients experienced AEs 12 months: All 5 patients had data at this time point; 1 of 5 patients (20%) experienced 1 AE: "high impedances on not active contact point" Last FU: All 5 patients had data at this time point; 0 of 5 experienced AEs **Stimulation related side effects, N (%):** 1-3 months: All 5 patients had data at this time point; 1 of 5 patients (20%) experienced 1 AE: "weird sensations in the mouth and tongue" 6 months: 3 of 5 patients had data at this time point; 2 of 3 patients (67%) experienced AEs (one each): "articulation and piano play worsened" and "right facial pulling" 12 months: All 5 patients had data at this time point; 0 of 5 experienced AEs Last FU: All 5 patients had data at this time point; 0 of 5 experienced AEs
Reference: Liker et al., 2024[5] **Country:** US (2 centers) **Study Design:** Prospective case series **Purpose:** To report the effects of a personalized surgical targeting procedure, Stereotactic Awake Basal Ganglia Electrophysiological Recording and Stimulation*, for patients with primary	**Sample size:** 30 total patients, 26 progressed to phase 3 (pulse generator implantation surgery) of which 2 had primary dystonia and were eligible for inclusion. *Demographic data were reported in aggregate for the entire study sample. **Mean age (range):** 13.5 (5, 20) years at time of phase 1 surgery (temporary stereotactic	**Intervention, N (%):** Medtronic Activa RC: 2 (100) **Comparator:** None **FU period (range):** 3 to 6 months post-operative	"No significant adverse events attributable to the staged surgical procedure or observation in the neuromodulation monitoring unit occurred."

Study Details	Patients	Study Characteristics	Outcomes Assessed
dystonia, secondary dystonia or Tourette syndrome **Funding:** Financial support from the Cerebral Palsy Research Alliance Foundation and the Crowley Carter Foundation. **COI:** None.	electrode placement) **Sex, N (%):** Female: 13 (43.3) Male: 17 (56.7) **Race/ethnicity N (%):** NR **Mean disease duration at DBS implantation (range):** NR **Diagnosis N (%):** Primary dystonia: 2 (6.7) **Inclusion criteria:** Patients identified as surgical candidates diagnosed by a pediatric movement disorder specialist based on established criteria and having confirmed failure of symptomatic medical therapy at adequate dosing. **Exclusion criteria:** NR		

Abbreviations: AE: adverse event; BFMDRS: Burke-Fahn-Marsden Dystonia Rating Scale; DBS: deep brain stimulation; FU: follow up; NR: not reported; SD: standard deviation.

Note: *Stereotactic Awake Basal Ganglia Electrophysiological Recording and Stimulation involved the following: phase 1 surgery, temporary stereotactic electrode placement; neuromodulation unit testing; phase 2 surgery, permanent deep brain stimulation electrode placement; phase 3 surgery, pulse generator placement; postoperative programming.