FDA Executive Summary

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

Minimally Invasive Deformity Correction (MID-C) System (H170001)

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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 Minimally Invasive Deformity Correction System ("MID-C") from ApiFix, Ltd. in pediatric patients since approval in 2019. 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 Humanitarian Device Exemption (HDE) remains appropriate for pediatric use. This document summarizes the safety data the FDA reviewed since HDE approval in October 2019. It includes data from the sponsor's Annual Report, post-market medical device reporting (MDR) of adverse events (AEs), peer-reviewed literature, and Post-Approval Study (PAS) data.

II. INDICATIONS FOR USE

Current Approved Indications for Use
The MID-C System is indicated for use in patients with adolescent idiopathic scoliosis (AIS) for treatment of single curves classified as Lenke 1 (thoracic major curve) or Lenke 5 (thoracolumbar/lumbar major curve), having a Cobb angle of 35 to 60 degrees which reduces to less than or equal to 30 degrees on lateral side-bending radiographs, and thoracic kyphosis less than 55 degrees as measured from T5-T12. Use of the MID-C System in patients with curves of lower magnitudes (i.e., less than 40 degrees) is based on the risk for curve progression.
Modifications from the Humanitarian Use Device (HUD) Designation & Original HDE Approval:
The Indication for Use statement was modified from that granted for the HUD designation. The Cobb angle criteria were updated from 45 to 60 degrees to 40 to 60 degrees. The major curve side-bending reduction criterion was updated to be more stringent (30 versus 35 degrees) to ensure a flexible curve. An additional statement was added to the Indications for Use ("Use of the MID-C System in patients with curves of lower magnitudes (i.e., less than 40 degrees) based on the risk for curve progression") in a regulatory submission after the original HDE approval. Since the original HDE approval, the sponsor further modified the Indications for Use to include Cobb angles as low as 35 degrees.

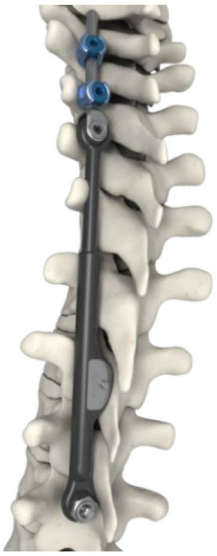
III. BRIEF DEVICE DESCRIPTION

The MID-C System is a non-fusion spinal device intended for treatment of adolescent idiopathic scoliosis and acts as an internal brace to achieve correction and stabilization of scoliotic deformity without the need for a spinal fusion. The device is a ratchet-based, expandable rod that attaches to the spine using two pedicle screws, one placed superior and one inferior to the apex of the curve. An optional extender is available composed of a 5.5mm rod and two pedicle screws to anchor the superior end of the implant with two screws rather than one. The MID-C System is made of titanium alloy (Ti-6Al-4V ELI) components, with some components coated in an amorphous diamond-like coating (ADLC). The device is implanted on the concave side of the spinal deformity, around the apex of a flexible single major curve, and acts as an internal brace to correct and stabilize scoliotic deformity via incremental ratchet lengthening. The system passively elongates when tensile load is applied via the pedicle screws and the length of the device expands in 1.3 mm increments. The ratchet and pawl mechanism permit one-way

elongation while maintaining the length of the device under compressive loads. In addition, the subject system includes instrumentation for insertion, manipulation, and removal of the implants.

Design Changes:
Design changes were approved and implemented in 2021, consisting of minor modifications to improve device manufacturability and strength, including updates to implant components (e.g., locking tooth, control shaft, base/pole configurations, and pedicle screws), minor instrumentation modifications, and the addition of an extender bender instrument. Additional design changes were approved in 2024, consisting of minor modifications to improve manufacturability, usability, and implant strength, including refinements to instrumentation, increased pole/base overlap to address a failure mode in the fully extended configuration, and other implant updates (e.g., added material at the pole mid-point).

Device Type	Image	Sizes	Material
Pedicle Screws		Lengths: 30-50mm (5mm increments) Diameters: 5.0-7.0mm (0.5mm increments)	Ti-6Al-4V ELI (ASTM F136) Coated with ADLC
MID-C System		Device Lengths (Extension Lengths): 85 mm (30) 95 mm (30) 105 (40) 115 (40) 125 (50)	Ti-6Al-4V ELI (ASTM F136) Coated with ADLC
Optional Extender		Configurations: 0° or 15° (left and right) Diameter: 5.5mm	Ti-6Al-4V ELI (ASTM F136)



IV. REGULATORY HISTORY AND CURRENT STATUS

The MID-C System received Humanitarian Use Device designation (HUD DEV-2015-0345) on December 21, 2015; however, an expansion of patient population was granted on November 14, 2019. The HDE was approved on August 20, 2019 (and the expanded patient population approved by supplement on December 16, 2019) by the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration. A summary of the HDE and PAS annual reports submitted for the MID-C System are presented in Table 1.

Table 1. H170001 Regulatory History

H170001 Reports	Status
PAS 6-Month Report	Report OK
HDE 1-year Annual Report	Report OK
PAS 12-Month Report	Report OK
PAS 18-Month Report	Report OK
PAS 24-Month Report	Report OK
HDE 2-year Annual Report	Report OK
PAS 36-Month Report	Report OK

HDE 3-year Annual Report	Report OK
PAS 48-Month Report	Report OK
HDE 4-year Annual Report	Report OK
PAS 60-Month Report	Report OK
HDE 5-year Annual Report	Report OK
PAS 72-Month Report	Report OK
HDE 6-year Annual Report	Report OK

V. SUMMARY OF CLINICAL DATA USED TO SUPPORT HDE APPROVAL

The MID-C System was implanted in 252 patients outside the US (OUS) as of September 15, 2018, and included clinical data from the following sources: (1) OUS prospective, multi-center, non-randomized, open label investigation in 20 subjects, (2) OUS commercial use on 197 patients, (3) OUS commercial use post-market prospective study on 26 subjects, and (4) OUS special access in 9 patients. Data from sources (2), (3), and (4) were obtained from post-market and commercial use outside of the US, with enrollment of patients inside and outside of the proposed US Indications for Use.

A target population (n=25) of all patients implanted with the MID-C System as of September 15, 2018, was initially identified to match the original proposed US indications for use with the following criteria:

Target Population Indications

- Lenke type 1 or 5 curves
- Risser grade 2 or above
- Pre-operative Cobb angle between 45 to 60 degrees (inclusive)
- Flexible major curve (defined as lateral bending correction of 30 degrees or less)
- Thoracic kyphosis less than 55 degrees

To capture a larger sample size, an expanded population (n=49) was included that met an expanded US Indications for Use, as approved by supplement on December 16, 2019, defined by the following criteria:

Expanded Target Population Indications

- Lenke type 1 or 5 curves
- Risser grade 2 or above
- Pre-operative Cobb angle between 40 to 60 degrees (inclusive)
- Flexible major curve (defined as lateral bending correction of 30 degrees or less)
- Thoracic kyphosis less than 55 degrees

The majority of the subjects were female (42/47, 89.4%), which is consistent with the known epidemiology of adolescent idiopathic scoliosis, where prevalence and curve severity are higher for adolescent females than for adolescent males.[8] The mean age at time of surgery was 15.0 years. Common primary assessments collected for all subjects were: skeletal maturity as determined by Risser grade and curve magnitude as determined by Cobb angle.

The prespecified primary probable benefit endpoint of the study was:

- Cobb angle at 24 months post-implantation, with success defined as a major Cobb angle of less than or equal to 35 degrees and no curve progression greater than 10 degrees compared to baseline.

To understand the probable benefits of the MID-C System more fully, ApiFix also conducted additional subgroup analyses that varied the Cobb angle threshold for use of the device as described above:

- Main Cobb angle ≤ 40° and no curve progression greater than 10° compared to baseline.
- Main Cobb angle ≤ 45° and no curve progression greater than 10° compared to baseline.
- Main Cobb angle ≤ 50° and no curve progression greater than 10° compared to baseline.

These additional endpoints were assessed based on published literature establishing 40-50° as thresholds used to assess the risk of subsequent curve progression.[1]

Individual subject success was defined as achievement of a Cobb angle less than or equal to 35 degrees at 24 months post-surgery. Six (6) out of the 8 subjects in the target population (75%) and 18 out of the 20 subjects in the expanded population (90%) with 24-month data met the success criteria in this study and were considered probable benefit successes. At the last follow-up visit greater than 24 months, all 20 patients in the expanded population had improvement of the primary Cobb angle (greater than 5 degrees compared to baseline), including the 2 patients who did not meet the primary probable benefit endpoint. The average improvement of the primary Cobb angle for these 20 patients is calculated as approximately 21 degrees compared to the average baseline Cobb angle of 45 degrees, resulting in approximately 40-50% curve correction. Furthermore, assessment of skeletal maturity concludes 86% of these patients were skeletally mature at the 24-month timepoint.

The primary safety endpoint evaluated was reoperation performed for any reason at any timepoint and included all serious adverse events (SAEs) that resulted in reoperation. In this clinical study AE data were classified as either device related AE or SAE. AE data were available for 63 patients and included 21 patients (33.3%) who reported an AE. The most common AE event types reported were pain (11/63, 17.5%), nausea and vomiting (3/63, 4.8%), and limited movement range of the spine (3/63, 4.8%). The non-serious AE data did not raise any notable safety concerns.

Reoperations occurred in 45 out of 252 subjects (17.9%). Many of these reoperations occurred early in the use of the device and were attributed to an initial technology learning curve. This learning curve is present with similar devices used for spinal fusion in AIS with re-operation rates as high as 17.1% reported in a five-year cohort[2]. However, when limiting the reoperation rate to the expanded population, the reoperation rate fell to 6 out of 49 subjects (12.2%) which is comparable to historical literature and database reported rate of 8.5% at 2-years for the target AIS population. No deaths or neurologic AEs were reported.

As the MID-C System is a non-fusion treatment, it offers patients the potential to avoid the long-term adverse consequences associated with fusion which include decreased spinal motion,

pseudarthrosis, adjacent spinal segment degeneration, neurological complications, pain, implant failure or breakage, and subsequent surgical intervention.

Patient perspectives were considered as an additional factor in the determination of probable benefits and risks for the device through the administration of patient questionnaires.

1. A patient satisfaction questionnaire was administered following the clinical study. Patients were asked to score their responses to three questions on a scale of 1 to 5, with 1 being the most negative response and 5 being the most positive. 36 out of 45 patients (80%) reported they agree or strongly agree that they would have the procedure again (scores of 4 or 5). Similarly, 38 of 45 patients (84%) agreed or strongly agreed that they would recommend the procedure to another person (scores of 4 or 5). Lastly, 38 of 45 patients (84%) rated their general satisfaction with the procedure/treatment as a 4 or 5.

2. Scoliosis Research Society (SRS-22) survey: The SRS-22 survey was collected for the 20 patients in the pilot study. This survey consists of 22 questions, which are grouped into the following sub-score categories: function, pain, self-image, mental health, and satisfaction with back management. For each sub-score, higher scores indicate more positive responses. Overall, there was consistent improvement across sub-scores to two years in both cohorts.

In conclusion, given the available information above, the data on the MID-C System collected under the studies support that the probable benefits outweigh the probable risks for use of this device for treatment of select patients with adolescent idiopathic scoliosis.

VI. POSTMARKET DATA: ANNUAL DISTRIBUTION NUMBER

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. Given that only one of the MID-C systems should be necessary to treat an individual, the total ADN for MID-C System is 8,000.

The 6-year HDE Annual Report was submitted on August 18, 2025, which included the Reporting Period from July 12, 2024, through July 16, 2025. The 72-Month PAS Report was submitted on August 11, 2025, and included the Reporting Period from August 23, 2019, through June 23, 2025. Table 2 provides the number of devices distributed in the sixth year (July 2024-July 2025). To date, there have been 396 HDE approved MID-C System devices distributed on the U.S. market, with the first patient treated with the device on June 30, 2020.

Table 2. Annual Distribution Number – Reporting Period: July 2024-July 2025

Device	Annual Distribution Limit	Reporting Period Total

		(7/2024-7/2025)
MID-C System	8,000	66

Of note: The first procedure conducted with the MID-C System was conducted OUS in April 2012. From that date until October 1, 2025, a total of 396 devices have been distributed in the US (with the first US patient treated on June 30. 2020), while a total of 1,087 devices have been distributed worldwide with the same number of procedures performed. Thus, 691 devices have been distributed OUS from April 2012 to October 1, 2025.

VII. POSTMARKET DATA: POST-APPROVAL STUDY (PAS)

PAS Conditions of Approval

The MID-C System HDE (H170001) was approved on August 20, 2019.

The objective of the PAS is to assess the ongoing safety and probable benefit of the MID-C System in a registry population.

The MID-C System Registry is a multi-center, single-arm, prospective post-approval registry study to provide ongoing safety and probable benefit assessment of the MID-C System in treatment of patients with adolescent idiopathic scoliosis. Skeletal maturity will be assessed using the Risser grade, Sanders score, or a combination of the two. All patients treated in the first 24-months should be enrolled and followed through 60-months from the time of each patient's index surgery, with interim visits at the immediate post-operative time point up to 6-weeks, 6-months, 12-months, and annually thereafter post-procedure. A minimum number of 200 patients will be enrolled in this study, with at least 50 patients enrolled by 24-months, 100 patients enrolled by 36-months (should enrollment still be ongoing), and 200 patients enrolled by 48-months (should enrollment still be ongoing). This study will include a minimum of 10 centers with sequential enrollment from each site that agrees to participate.

The primary safety endpoints are SAEs and device- or procedure-related AEs. Additional safety analyses will include the: rate of AEs, including by relatedness to device or procedure, AE severity and rate of reoperation, including by type of reoperation.

The current primary probable benefit endpoint identified as a Condition of Approval in the HDE Approval Order is maintenance of major Cobb angle less than or equal to 40 degrees at 60-months post-surgery.

Secondary endpoints will be analyzed annually up to 60-months post-surgery, and will include the following:

1. Maintenance of major Cobb angle less than or equal to 40 degrees.
2. Curve progression no greater than 10 degrees of the secondary curve above or below the implant.

3. Composite endpoint analysis (maintenance of major Cobb angle less than or equal to 40 degrees AND freedom from SAEs during MID-C System procedure and procedure/device related SAEs following surgery).
4. Analysis of the failure attributable to conversion to another spinal implant OR major Cobb angle that exceeded 40 degrees at defined follow-up visit OR any curve progression at defined follow-up compared to baseline OR death OR permanent disability.

All safety and probable benefit data will be collected at the following time points: pre-operative, immediate post-operative up to 6-weeks, 6-months, 12-months, and annually thereafter until 60-month post-operative data from each patient are collected. This study is estimated to last a total of 84-months. Descriptive statistics and 95% confidence intervals will be presented for all analyses. For continuous variables, means and standard deviations will be shown. For categorical variables, frequencies and percentages will be presented.

The study population is comprised of pediatric patients (defined as persons younger than 22 years of age) that require surgical treatment or have failed non-surgical treatments to obtain and maintain correction of progressive spinal deformities with a Cobb angle of 30-60 degrees, with a flexible curve, and thoracic kyphosis less than 55 degrees, as measured from T5 to T12.

PAS Study Status

The original PAS protocol was accepted on October 23, 2019, and the seventy-two-month PAS report was approved on September 09, 2025. As of this date, thirteen (13) sites have study IRB approval with a total 201 patients enrolled. Enrollment of this PAS is complete and the study is estimated to last a total of 84 months from the date of PAS approval.

Patient demographics and follow-up are summarized below in Table 3 and Table 4.

Table 3. PAS Patient Demographics

Patient Demographics	
N	201
Age (years) at Surgery	14.9 ± 2.1
Sex	74% (149/201) Females 26% (52/201) Males
Risser Sign	0 – 19% (38/201) 1 – 5% (11/201) 2 – 7% (14/201) 3 – 15% (30/201) 4 – 32% (64/201) 5 – 22% (44/201)
Lenke Class	67% (134/201) Lenke 1 33% (67/201) Lenke 5

Source: Constructed based on data from H170001 annual reports

Table 4. PAS Patient Follow-up Status

Patient Follow-up per Study Visit	
Study Visit	Completed
Pre-Op	201
6-week	201
6-month	201
12-month	201
24-month	173
36-month	130
48-month	76
60-month	9

Source: Constructed based on data from H170001 annual reports

Interim Results:

Probable Benefit:

At the 6-week visit, the average major Cobb angle was 19.0° ± 6.9°. Most patients successfully maintained a major Cobb angle <40° at all follow-up timepoints, with maintenance rates of 100% at 6 months, 98% at 12 months, 96% at 24 and 36 months, and 88% at 48 months (Table 5). In the majority of cases, the secondary curve Cobb angle was reduced or didn't increase above 10° compared to the preoperative value in 99% (199/201) of patients at the last available follow-up (Table 6).

Table 5. PAS Probable Benefit Summary: Major Cobb Angle

Major Cobb Angle							
	Pre-Op	6-week	6-month	12-month	24-month	36-month	48-month
N	201	199	189	175	115	68	16
Cobb Angle	45.5 ± 6.5°	19.0 ± 6.9°	17.7 ± 8.2°	17.1 ± 9.0°	19.6 ± 10.1°	20.2 ± 10.8°	22.8 ± 12.6°
% with Cobb Angle < 40°	—	—	100%	98%	96%	96%	88%

Source: Constructed based on data from H170001 annual reports

Table 6. PAS Probable Benefit Summary: Secondary Cobb Angle

Secondary Cobb Angle							
	Pre-Op	6-week	6-month	12-month	24-month	36-month	48-month
N	201	198	187	175	115	68	16
Cobb Angle	30.2 ± 7.3°	18.2 ± 9.6°	18.2 ± 9.5°	17.9± 10.4	19.5± 10.6	19.5± 10.6	19.2 ± 10.1°

Source: Constructed based on data from H170001 annual reports

Safety:

Within the PAS (N=201 patients enrolled), 159 adverse events (AEs) were reported in 102 subjects (51%), along with 9 elective implant-removal procedures without reported patient harm. Of the 159 events, 79 (50%) were classified as serious adverse events (SAEs) requiring reoperation, and 80 (50%) were classified as non-serious. All of the SAEs that resulted in reoperations are reported below.

Reoperations:
There were 79 reoperations in 64 patients, with 15 patients requiring two reoperations. The reoperation rate increased over time in the study population: from 15% in the 2023 report (PAS 48-Month Report) to 22% in the 2024 report (PAS 60- Month Report), and 32% in the current 2025 report (PAS 72- Month Report). The average follow-up length was 37 months.

The leading reasons for reoperation included:

- **Implant Breakage**: 25 events (device-related)
- **Screw migration/misplacement/loosening/pull-out/breakage**: 17 events (device-related)
- **Curve progression/insufficient correction/spinal imbalance**: 11 events (9 device-related, 2 procedure-related)
- **Ratchet Malfunction**: 11 events (device-related)
- **Pain**: 6 events (device-related)
- **Wound complication/Late infection/superficial infection**: 6 events

Of the 79 reoperations, 68 (86%) were classified as device-related and 2 (2.5%) as procedure-related. Among the 79 reoperations performed 20 (25%) were revisions to a new MID-C system and 21 (27%) involved removal of the MID-C system. As described above in the Device Description section, design changes to the device were approved and have been implanted. Subjects in the PAS include both the original design along with the current design. However, longer term follow-up of subjects implanted with the current design is not yet available. Additional follow-up is needed to compare the long-term performance of the two designs.

Non-Serious Adverse Events:
Of the 80 non-serious adverse events, 66 (83%) were resolved, 13 (16%) had missing data and are currently under query, and 1 (1%) remained ongoing. The most frequent non-serious AE was pain (41 events), which can be device-related, procedure-related, or unrelated. Other non-serious AEs included tissue irritation/wound complications (15 events), discomfort (6 events), and implant prominence (2 events).

Elective Implant Removals:
Nine patients elected to have their implants removed at an average of 49 months after the index procedure. Post-removal data available for 3 of these 9 patients showed curves less than 40°. These patients continue to be followed through the 5-year post-index surgery timepoint.

VIII. ADVERSE EVENTS

Known Adverse Events

AEs collected during the clinical study that were used to support the safety and probable benefit of MID-C System in patients with adolescent idiopathic scoliosis were presented in the SSPB at the time of approval. For the initial target study population (n=252), 45 patients (17.9%) required reoperation. For the expanded target study population (n=49), 6 patients (12.2%) required reoperation. Table 7 lists all AE types reported in the clinical study, or identified by clinical experts, that were classified as related to the device or procedure.

Table 7. Known Adverse Event Types

AEs Related to Device or Procedure	Systemic AEs
1. Screw/nut loosening 2. Device loosening, migration, breakage, malposition 3. Sizing issues 4. Anatomic/technical difficulty 5. Inability to implant the device 6. Intraoperative device revision 7. Loss or inadequate curve correction 8. Curve development above and/or below the instrumented levels 9. Requirement for subsequent surgical intervention 10. Neurologic 11. Heterotopic ossification 12. Trunk imbalance 13. Interference with imaging 14. Unintended spontaneous fusion 15. Bone fracture 16. Dural tear/leakage 17. Surgical site seroma, bursitis, crepitus 18. Skin penetration by device 19. Wound dehiscence 20. Hematoma 21. Wound infection, superficial, deep 22. Intraoperative neurologic injury 23. Intraoperative vascular injury, excessive blood loss, hypotension 24. Anesthesia, airway, ventilation 25. Visceral injury 26. Blood transfusion 27. Allergic reaction 28. Ophthalmic injury, including blindness	1. Deep vein thrombosis 2. Pulmonary embolism 3. Atelectasis, pneumonia 4. Cardiac 5. Dysphagia 6. Dysphonia 7. Gastrointestinal (ileus, ulceration, bleeding, malnutrition) 8. Foreign body reaction 9. Pressure sores 10. Genitourinary (infection, urine retention) 11. CSF leak/meningocele 12. Chest tube insertion 13. Infection (systemic) 14. Hematologic 15. Endocrine/metabolic 16. Hepatobiliary 17. Immunologic 18. Gynecologic 19. Ophthalmologic 20. Psychological 21. Surgical procedure: non-spinal 22. Wound infection: non-spinal 23. Death

29. Pain (back, surgical site, extremity, other) 30. Infection 31. Device malfunction 32. Screw pull-out	

From the AEs reported in Table 7, Table 8 summarizes the six (6) AE types that were classified as device or procedure-related SAEs. All SAEs required reoperation with device loosening, migration, breakage, and malposition being the most common (9/252, 3.6%) followed by loss or inadequate curve correction (8/252, 3.2%), infection (8/252, 3.2%), device malfunctions (6/252, 2.4%), screw pull-out (5/252, 2%), and screw/nut loosening (5/252, 2%). When restricting the analysis to patients who met the expanded US indications, the most common SAE requiring reoperation was procedure related (5/49, 10.2%) followed by device related (1/49, 2%).

Table 8. Known SAE Types Related to the MID-C System or Procedure

SAEs Related to MID-C System or Procedure
1. Device loosening, migration, breakage, malposition 2. Loss or inadequate curve correction 3. Infection 4. Device malfunctions 5. Screw pull-out 6. Screw/nut loosening

Note: *These SAE types were identified in the pre-market clinical study. Post-market surveillance through the PAS (n=201 US patients) has identified the same categories of SAEs, with no new unanticipated adverse event types. The most common post-market SAEs requiring reoperation include implant breakage, screw-related complications, curve progression, and ratchet malfunction, consistent with the known risk profile.*

Literature Review

A clinical literature search in PubMed was performed by the FDA for articles published from October 1, 2024, through October 1, 2025. The following terms were used: “ApiFix”, “MID-C”, “QGP”, “Posterior Ratcheting Rod System”. The following inclusion/exclusion criteria were used to further refine the articles to ones relevant for this HDE:

Inclusion Criteria:

- It provides relevant information regarding technical and clinical features of the device subject of the search, or
- It provides relevant information regarding performance and/or safety of the device subject of the Search, or
- It provides information relevant to determining the probable benefit of the subject device, and
- It contains sufficient information for a rational and objective assessment, and
- It is based on an appropriate study design.

Exclusion Criteria:

- Those involving implants other than those of interest

- Isolated case reports
- Random experience
- Reports lacking sufficient detail to permit scientific evaluation
- Unsubstantiated opinions
- Non-clinical studies
- Review papers
- Tethered spinal cord studies
- Foreign language (non-English) literature

Following review of titles, abstracts, and full texts identified through the PubMed search and application of inclusion and exclusion criteria, two clinical articles relevant to the ApiFix MID-C System were identified during the current reporting period.[6,7] In both publications, the term "posterior dynamic distraction device" (PDDD) is used as a descriptive term rather than a branded device name.

Across the two studies, patients were followed for approximately two years post-implantation. One study evaluated motion preservation following PDDD implantation, demonstrating maintenance of coronal and sagittal spinal motion across instrumented segments without radiographic evidence of autofusion (N=11 PDDD patients; mean follow-up 1.9 years).[6] The second study was a prospective, matched comparative cohort analysis of two FDA HDE-approved non-fusion systems (PDDD and vertebral body tethering), which reported radiographic outcomes, perioperative parameters, and revision surgery rates (N=20 PDDD vs N=20 VBT).[7]

The types of adverse events reported in these publications, such as device loosening or failure, inadequate correction or loss of curve correction, and revision or reoperation, are consistent with the adverse events previously identified in the Summary of Safety and Probable Benefit (SSPB) for the MID-C System, including device migration or breakage, loss of correction, and the requirement for subsequent surgical intervention. All adverse event types described in the literature were identified at the time of HDE approval as potential risks associated with the device.

Overview of MDR Database

Strengths and Limitations of MDR Data

Each year, the FDA receives several hundred thousand MDRs of suspected device-associated deaths, serious injuries, and malfunctions. The MDR database houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters such as health care professionals, patients, and consumers. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of regulated devices. MDR reports can be used effectively to:

- Establish a qualitative snapshot of adverse events for a specific device or device type
- Detect actual or potential device problems used in a "real world" setting/environment, including:
    - Rare, serious, or unexpected adverse events;
    - Adverse events that occur during long-term device use;

- Adverse events associated with vulnerable populations;
- Off-label use; and
- Use error

Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use. Because of this, MDRs comprise only one of the FDA's several important post-market surveillance data sources. Other limitations of MDRs and FDA's internal MDR database include:

- MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time, or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices.
- Confirming whether a device caused a specific event can be difficult based solely on information provided in each report. Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated.
- MDR data is subjected to reporting bias, attributable to potential causes such as reporting practice, increased media attention, and/or other agency regulatory actions.
- 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.

MDRs Associated with the MID-C System

The FDA's internal MDR Database was searched on December 12, 2025, utilizing the following search criteria:

1. Manufacturer Name ("ApiFix") and Brand Name ("MID-C")
    - 53 unique MDRs were found.
2. Manufacturer or Company Name ("ApiFix")
    - No events not already contained in search criterion 1.
3. Brand Name or Generic Name or Concomitant Product containing "MID-C."
    - No events not already contained in search criterion 1.
4. PMA/510K: "H170001" OR "170001"
    - No events pertaining to MID-C not already contained in search criterion 1.

The search resulted in fifty-three (53) MDRs, all of which occurred from October 15, 2024 to October 1, 2025. Thirty-four (34) MDRs took place within the US, while nineteen (19) MDRs took place OUS.

A summary of all 34 unique US MDRs this year is shown in Table 9.

Table 9. US MDRs for the MID-C

Adverse Event Type	Number of Events	Source

Implant Breakage	8	FDA's internal MDR search
Screw Loosening	1	FDA's internal MDR search
Ratchet Malfunction	7	FDA's internal MDR search
Pain	1	FDA's internal MDR search
Conversion to Fusion	2	FDA's internal MDR search
Infection	2	FDA's internal MDR search
Device Replaced w/ longer MID-C construct	2	FDA's internal MDR search
Skeletally Mature / Maximum Elongation Reached	8	FDA's internal MDR search
Planned Explantation or Elective Removal	3	FDA's internal MDR search
Total	34	FDA's internal MDR search

Outside of the United States (OUS) MDRs

It is important to note that a significant number of devices implanted OUS are of an older MID-C device generation with a wider range of Indications for Use. A higher rate of AEs was observed in devices implanted OUS compared to those approved in the US. As such, OUS AEs are not necessarily indicative of current or future US AEs; however, they are useful to examine. A summary of all 19 unique OUS MDRs this year is shown in Table 10.

Table 10. OUS MDRs for the MID-C

Adverse Event Type	Number of Events	Source
Infection	1	FDA's internal MDR search
Skeletally Mature / Maximum Elongation Reached	4	FDA's internal MDR search
Ratchet Malfunction	4	FDA's internal MDR search
Screw Migration	1	FDA's internal MDR search
Screw Loosening	1	FDA's internal MDR search
Planned Explantation or Elective Removal	4	FDA's internal MDR search
Screw Fracture	1	FDA's internal MDR search
Conversion to Fusion	1	FDA's internal MDR search
Pain	2	FDA's internal MDR search
Total	19	FDA's internal MDR search

Discussion on Black Residue/Black Discoloration The black residue/black discoloration in the tissue surrounding the MID-C system was noted in 2022 via two MDRs, in 2023 via one MDR, in 2024 via three MDRs, and in 2025 via one MDR. ApiFix attributes this to Amorphous Diamond-Like Coating (ADLC) wear, which was a known occurrence at HDE approval. All moving titanium components of the MID-C System are coated with an ADLC layer to improve wear resistance (Table 11).

Histopathological analysis of 15 tissue samples collected during reoperation procedures demonstrated low inflammatory reactions (average scores: polymorphonuclear cells 0.3,

lymphocytes 0.5, macrophages 0.8, and necrosis 0.3 on a 0-4 scale). One patient sample showed an elevated inflammatory response due to a confirmed bacterial infection (E. coli), not related to the coating material. The presence of microscopic wear debris is expected in motion-preserving implants and is consistent with other spinal instrumentation systems. All black discoloration observations were incidental findings during reoperation for other primary events and have not been attributed to symptomatic adverse events. Tissue discoloration observations for this device were studied in 2024 where it was concluded that these findings were not expected to promote device failure.[9] FDA will continue to monitor tissue response data as additional PAS patients reach longer-term follow-up.

Table 11. ADLC Coated Components of the ApiFix Rod

Device Region	Image
Base	
Pole	
Spherical Ring	

True Failure Analysis True failure rate analysis was performed for all patients with X-ray measurements available in the ApiFix registry. Patients with missing data or available X-rays that were not yet measured were not accounted for in the analysis. Per the study protocol, true failure is defined as conversion to another spinal implant (not the MID-C system) OR major Cobb angle that exceeded 40° at a defined follow-up visit OR any curve progression at a defined follow-up compared to baseline OR death, OR permanent disability. While true failure was defined by the sponsor as described above, device failures (e.g., breakage) are still captured in this analysis and reported through MDRs. Table 12 demonstrates true failure rates of 0%, 3%, 15%, 26%, and 56% at 6-months, 12-months, 24-months, 36-months, and 48-months, respectively.

Table 12. True Failure Rate Analysis

Population	Visit	Success		Failure		All	
		n	%	n	%	N	%
PAS all population	6 months	189	100%	0	0%	189	100%
	12 months	172	97%	6	3%	178	100%
	24 months	106	85%	18	15%	124	100%
	36 months	65	74%	23	26%	88	100%
	48 months	15	44%	19	56%	34	100%
	Total	174	87%	27	13%	201	100%

Summary of MDRs

As of October 1, 2025, a total of three hundred and four (304) worldwide MDRs have been identified related to the ApiFix MID-C System since HDE approval. Though the discoloration of tissue reported in previous years and this year in two MDRs can be a sign of metallosis and additional safety concerns, the discoloration presented by the MID-C System is not an unanticipated finding for metallic implants with ADLC coatings and does not appear to be harmful based on available data. However, additional monitoring will be conducted as minimal data has been collected in the US with only 396 subjects currently implanted and only 175 and 115 subjects reporting data out to 12 months and 24 months respectively (as of August 2025). Table 13 summarizes all MDRs associated with the MID-C System. As of October 2025, the MDRs reported represent a 30.3% rate in the US and a 27.97% rate worldwide most resulting in reoperation. While the MDR rate is not a direct view of the AE rate, it is higher than the AE rate in the Summary of Safety and Probable Benefit (SSPB) for the MID-C HDE which showed a 12.2% AE rate in the US and a 17.9% AE rate worldwide.[4] By comparison, spinal fusion surgery for AIS can expect a reoperation rate of 4.1% at 24-months[3] and 9.9% at 60-months[2], while The Tether™ –Vertebral Body Tethering System, a non-fusion spinal device intended for treatment of AIS, has a secondary surgery rate, composed of both revisions and reoperations, of 14.0%.[5] The increase in the MID-C System MDR rate is higher than the AE rate for both fusion and other non-fusion spinal devices, but does not appear to present a new safety signal at this time and will be closely monitored.

Table 13. MDR Rate

	Total (OUS and US)		US	
	MDRs	Rate	MDRs	Rate
Up to December 1, 2021	62	10.37% (62/598)	5	5.26% (5/95)

December 1, 2021 – October 1, 2022	56	43.08% (56/130)	15	20.27% (15/74)
October 2, 2022 – October 1, 2023	74	50.64% (74/133)	31	36.47% (31/85)
October 2, 2023 – October 1, 2024	59	51.75% (59/114)	35	49.30% (35/71)
October 2, 2024 – October 1, 2025	53	47.32% (53/112)	34	47.89% (34/71)
Cumulative	304	27.97% (304/1087)	120	30.30% (120/396)

IX. SUMMARY

Evaluation of data available to CDRH, including the HDE 6-year Annual Report, MDRs, published scientific literature, and correspondence with the sponsor, has identified no new safety signals compared to what was known and anticipated at the time of HDE approval in August 2019. Additionally, the MID-C System underwent design changes and surgical technique updates since HDE approval which were intended to mitigate early known AEs and improve the safety and probable benefit profile of the device. Based on the available data, and considering the probable benefits – including avoidance of a definitive fusion procedure - and risks, the FDA believes that the HDE remains appropriately approved for pediatric use.

Therefore, FDA recommends continued surveillance and will report the following to the PAC in 2027:

- Annual distribution number
- Literature review
- MDR review
- Update on the PAS

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