SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Human Papillomavirus RNA detection kit

Device Trade Name: Aptima HPV Assay

Device Procode: OYB

Applicant's Name and Address:

Hologic, Inc.
10210 Genetic Center Drive
San Diego, California 92121

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P100042/S038

Date of FDA Notice of Approval: February 3, 2026

The original PMA P100042 was approved on October 28, 2011. P100042/S001 was approved on July 15, 2013, for the addition of the Panther system. P100042/S013 was approved on February 28, 2018, for the addition of the Panther Fusion Module.

P100042/S024 was approved on December 16, 2019, for the addition of a Multi-tube unit (MTU) sidecar, Continuous Fluids Module, Waste-to-Drain Module, and Shuttle Module to the Panther and Panther Fusion instruments. P100042/S034 was approved on June 2, 2023, for the addition of manual post-cytology aliquot, pre-cytology aliquot and post-cytology aliquot removed by the ThinPrep Genesis Processor as acceptable samples.

The SSED to support the original PMA is available on the CDRH website and is incorporated by reference here
https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100042B.pdf

Based on these premarket applications, the Aptima HPV assay is indicated for:
The Aptima HPV assay is an in vitro nucleic acid amplification test for the qualitative detection of E6/E7 viral messenger RNA (mRNA) from 14 high-risk types of human papillomavirus (HPV) in cervical specimens. The high-risk HPV types detected by the assay include: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. The Aptima HPV assay does not discriminate between the 14 high-risk types. Cervical specimens in ThinPrep Pap Test vials containing PreservCyt Solution and collected with broom-type or cytobrush/spatula collection devices may be tested with the Aptima HPV assay. The assay is used with the Tigris DTS System or the Panther System.
The use of the test is indicated:

1. To screen women 21 years and older with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to determine the need for referral to colposcopy. The results of this test are not intended to prevent women from proceeding to colposcopy.

2. In women 30 years and older, the Aptima HPV assay can be used with cervical cytology to adjunctively screen to assess the presence or absence of high-risk HPV types. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management.

The current supplement was submitted to expand the indication for the Aptima HPV assay to include primary screening for women 25 years and older.

II. INDICATIONS FOR USE

The Aptima HPV Assay is an in vitro nucleic acid amplification test for the qualitative detection of E6/E7 viral messenger RNA (mRNA) from 14 high-risk types of human papillomavirus (HPV) in cervical specimens. The high-risk HPV types detected by the assay include: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. The Aptima HPV Assay does not differentiate between the 14 high-risk types. Cervical specimens in ThinPrep® Pap Test vials containing PreservCyt® Solution and collected with broom-type or cytobrush/spatula collection devices* may be tested with the Aptima HPV Assay. The assay is used with the Tigris DTS System or the Panther System.

The Aptima HPV Assay is indicated for use for routine cervical cancer screening as per professional medical guidelines, including triage of ASC-US cytology, co-testing (adjunctive screening) with cytology, and HPV primary screening of women to assess the risk for cervical pre-cancer and cancer.

Patients should be followed-up in accordance with professional medical guidelines, results from prior screening, medical history, and other risk factors.

Primary HPV screening with the Aptima HPV Assay has only been validated on the Panther System.

* Broom-type device (e.g., Wallach Papette®) or endocervical brush/spatula.

III. CONTRAINDICATIONS

None.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Aptima HPV Assay labeling.

V. DEVICE DESCRIPTION

The device is an in vitro nucleic acid amplification test for qualitative detection of E6/E7 viral messenger RNA (mRNA) from 14 high-risk types of HPV in cervical specimens. The Aptima HPV Assay involves three main steps, which take place in a single tube: target capture; target amplification by Transcription-Mediated Amplification (TMA); and detection of the amplification products (amplicon) by the Hybridization Protection Assay (HPA). The assay incorporates an internal control to monitor nucleic acid capture, amplification, and detection, as well as operator or instrument error.

Specimens are transferred to a tube containing Specimen Transport Media (STM) that lyses the cells, releases the mRNA, and protects it from degradation during storage. When the Aptima HPV Assay is performed, the target mRNA is isolated from the specimen by use of capture oligomers that are linked to magnetic microparticles. The capture oligomers contain sequences complementary to specific regions of the HPV mRNA target molecules as well as a string of deoxyadenosine residues. During the hybridization step, the sequence-specific regions of the capture oligomers bind to specific regions of the HPV mRNA target molecule. The capture oligomer-target complex is then captured out of solution by decreasing the temperature of the reaction to room temperature. This temperature reduction allows hybridization to occur between the deoxyadenosine region on the capture oligomer and the poly-deoxythymidine molecules that are covalently attached to the magnetic particles. The microparticles, including the captured HPV mRNA target molecules bound to them, are pulled to the side of the reaction tube using magnets and the supernatant is aspirated. The particles are washed to remove residual specimen matrix that may contain amplification inhibitors.

After target capture is complete, the HPV mRNA is amplified using TMA, which is a transcription-based nucleic acid amplification method that utilizes two enzymes, MMLV reverse transcriptase and T7 RNA polymerase. The reverse transcriptase is used to generate a DNA copy of the target mRNA sequence containing a promoter sequence for T7 RNA polymerase. T7 RNA polymerase produces multiple copies of RNA amplicon from the DNA copy template.

Detection of the amplicon is achieved by HPA using single-stranded nucleic acid probes with chemiluminescent labels that are complementary to the amplicon. The labeled nucleic acid probes hybridize specifically to the amplicon. The Selection Reagent differentiates between hybridized and unhybridized probes by inactivating the label on the unhybridized probes. During the detection step, light emitted from the labeled RNA-DNA hybrids is measured as photon signals called Relative Light Units (RLU) in a luminometer. Final assay results are interpreted based on the analyte signal-to-cutoff (S/CO).

Internal Control is added to each reaction via the Target Capture Reagent. The Internal Control monitors the target capture, amplification, and detection steps of the assay. Internal Control signal in each reaction is discriminated from the HPV signal by the differential kinetics of light emission from probes with different labels. Internal Control-

specific amplicon is detected using a probe with a rapid emission of light (flasher). Amplicon specific to HPV is detected using probes with relatively slower kinetics of light emission (glower). The Dual Kinetic Assay (DKA) is the method used to differentiate between the signals from the flasher and glower labels.

Test Interpretation
Assay test results are automatically determined by the assay software. A test result may be negative, positive, or invalid, as determined by the Internal Control (IC) RLU and the signal-to-cutoff (S/CO) for the Analyte. A test result may also be invalid due to other parameters (abnormal kinetic curve shape) being outside the normal expected ranges. Invalid test results should be repeated.

Aptima HPV Assay Result	**Criteria**
Negative	Analyte S/CO < 0.50 IC ≥ IC cutoff IC ≤ 2,000,000 RLU
Positive	Analyte S/CO ≥ 0.50 IC ≤ 2,000,000 RLU Analyte ≤ 13,000,000 RLU
Invalid	Analyte S/CO < 0.50 AND IC > 2,000,000 RLU OR Analyte > 13,000,000 RLU

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several alternatives for the detection of cervical cancer precursors, including testing by cytology alone, co-testing with HPV alongside or as a follow-up to cytology, or HPV testing as a first line screening test for cervical cancer. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with a physician to select the method that best meets expectations and lifestyle.

The patient's age, medical history and thorough physical examination will provide further information on the risk of cervical disease, as well as the need for referral to colposcopy. The Aptima HPV Assay should only be used in conjunction with this clinical information in accordance with appropriate clinical patient management guidelines.

VII. MARKETING HISTORY

As of January 2026, the Aptima HPV Assay is approved for sale in the following countries:

Australia	India	Portugal
Austria	Indonesia	Puerto Rico
Belgium	Ireland	Romania
Botswana	Israel	Russia
Brazil	Italy	Saudi Arabia

Bulgaria	Japan	Serbia
Canada	Kenya	Singapore
China	Korea	Slovakia (Slovak Republic)
Colombia	Kuwait	Slovenia
Costa	Rica Latvia	South Africa
Croatia	Liechtenstein	Spain
Cyprus	Lithuania	Sweden
Czech Republic	Luxembourg	Switzerland
Denmark	Malaysia	Taiwan
Estonia	Malta	Thailand
Finland	Mexico	Turkey
France	Netherlands	Uganda
Germany	Nigeria	United Kingdom
Greece	Norway	United States of America
Hong Kong	Pakistan	Vietnam
Hungary	Panama	Zambia
Iceland	Poland	Zimbabwe

The Aptima HPV Assay has not been withdrawn from these markets for any reason.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

The following section outlines the potential adverse effects (e.g., complications) associated with the use of the Aptima HPV Assay. As with any in vitro diagnostic test, the potential adverse effects are associated with incorrect test results or result interpretations. Failure of this device to perform as expected or failure to correctly interpret results may lead to incorrect HPV test results and subsequently, improper patient management decisions in cervical cancer screening. False negative results may lead to delays in the timely diagnosis of cervical cancer, allowing an undetected condition to worsen and potentially increasing morbidity and mortality. False positive results could lead many patients to unnecessarily undergo more frequent screening and potentially invasive procedures such as colposcopy and biopsy.

IX. SUMMARY OF PRIMARY CLINICAL STUDY

The establishment of a reasonable assurance of safety and effectiveness of the Aptima HPV Assay on the Panther System as an HPV primary screening test is based on a multicenter Real-World Data (RWD) study called the REACH study. Data from this study along with benefit-risk assessment were the basis for the PMA approval decision. A summary of the REACH study is presented below.

A. Study Design

Use of the Aptima HPV Assay on the Panther System as a primary cervical cancer screening test (primary screening) was evaluated using data collected in the U.S. in a large retrospective, multicenter RWD study, known as the REACH study.

The REACH study was conducted to evaluate the clinical performance of the Aptima HPV Assay compared to an FDA-approved HPV DNA test for primary screening. Data for the Aptima and FDA-approved HPV DNA test (comparator cohort) cohorts were obtained from 8 sites (5 sites for Aptima, 2 sites for comparator cohort, 1 site that included both) which included integrated data networks (IDNs), hospital systems, and large medical practices representing a wide geographic distribution and a diverse enrollment population (7 states within the US).

Women ≥25 years of age, who underwent cervical cancer screening with an HPV assay result and liquid-based cytology in routine clinical practice were assessed for eligibility. Women were excluded if they had a known history of cervical biopsy, cytology and/or HPV test of any result within 300 days prior to the index HPV test (the first HPV test result for a patient that meets study eligibility); cervical cancer, ablative or excisional treatment or surgery to the cervix, and/or hysterectomy prior to or on the date of the index HPV test. Any woman with a histology result available within 0 to 6 days of the index HPV test was excluded.

All data were extracted in a retrospective manner from information routinely collected in the electronic medical records.

Because only women who had both cytology and HPV test results as part of routine cervical cancer screening were enrolled, there was a potential for selection bias, with a higher likelihood among those aged 25 – 29 years old. This is a result of medical guidelines recommending screening by ASC-US triage for those aged 25 – 29 years old. To ensure that the disease risk/prevalence between Aptima HPV and comparator cohorts was comparable, the estimates were adjusted for cytology and the analyses were performed for two age populations (25 – 29 years and 30 years and older).

The study's outcome was cervical disease defined as ≥CIN3 and ≥CIN2.

1. Determination of Disease Status

   Cervical disease status (≥CIN2 or ≥CIN3) at baseline was determined by the most severe histology result available between 7 days and 12 weeks (84 days) of the index (first valid) HPV test result. Cervical disease status (<CIN2) at baseline was determined by either colposcopic evaluation not requiring histology or histology result (<CIN2) available between 7 days and 12 weeks (84 days) of the index (first valid) HPV test result.

   Multiple imputation was performed for women with a positive index HPV test and missing cervical disease status during this time period.

2. Clinical Endpoints

With regards to safety, the Aptima HPV Assay involves sampling cells from the cervix using broom-type or cytobrush/spatula collection devices. The test, when used as part of HPV primary screening, presents no more safety hazard to an individual being tested than when used as part of triage of ASC-US cytology or co-testing. Safety issues regarding false positive and negative test results are discussed in section XII part B.

With regards to effectiveness, the performance of the Aptima HPV Assay was evaluated based on the ratios of clinical sensitivities (ratios of true positive rates) and the ratios of false positive rates between the Aptima HPV Assay and the FDA-approved HPV test for both ≥CIN3 and ≥CIN2 clinical outcomes. For both the Aptima HPV Assay and the FDA-approved HPV test, a woman was considered as having a positive primary screening result as shown in Table 1.

Table 1: Determination of a Positive Primary Screening Result.

		Cytology Result			
		>ASC-US	**ASC-US**	**UNSAT**	**NILM**
Aptima HPV Test Result	**HPV16/18 45**	Positive	Positive	Positive	Positive
	11 Other	Positive	Positive	Positive	Negative
	Negative	Negative	Negative	Negative	Negative
FDA-Approved Test Result	**HPV16/18**	Positive	Positive	Positive	Positive
	12 other	Positive	Positive	Positive	Negative
	Negative	Negative	Negative	Negative	Negative

For women with Aptima HPV Assay positive results and where genotyping was required, an Aptima HPV 16 18/45 Genotype Assay result was used to determine HPV genotype (categorized as HPV 16, HPV 18/45, or 11 other high-risk HPV types). The two-sided 95% confidence intervals for the ratios of clinical sensitivities and the ratios of false positive rates were calculated using the bootstrap method. Analyses were performed for the two age populations (25 – 29 years and 30 years and older) adjusted for cytology.

B. Accountability of PMA Cohort

The number of women assessed for eligibility was 543,233 for the Aptima HPV Assay cohort and 223,596 for the comparator cohort. In total, 470,468 and 190,053 women in the Aptima HPV cohort and the comparator cohort, respectively, who were 25 years of age and older were evaluable and enrolled in the REACH study. See Table 2 for patient attrition by cohort.

Table 2. Patient Attrition by Study Cohort.

			Aptima HPV Assay	**Comparator cohort**
Number of women assessed for eligibility			543,233	223,596
EXCLUDED			72,765	33,543
Exclusions	One of the exclusion reasons below		58,309	27,965
	Multiple of the exclusion reasons below		14,456	5,578
		Invalid HPV results	161	288

	Exclusion Reasons	No baseline co-test with valid results	9,809	4,060
		History of cervical biopsy/cytology/HPV test in the 300 days prior to index test	23,764	6,152
		Age <25 years as of index date	10,551	3,463
		History of cervical cancer prior to or on index date	3,727	3,213
		History of ablative or excisional treatment prior to or on index date	39,243	19,582
		History of hysterectomy prior to or on index date	23,883	11,020
		Removed inadvertently from EDC by site PI	1	0
		Incomplete HPV result	0	5
		Baseline histology within 0-6 days	1883	836
		Incomplete co-test result	0	18
Number of eligible women included in the study analysis			470,468	190,053

C. Study Population Demographics and Baseline Parameters

Table 3 describes the REACH population by age and cytology results. Table 4 describes the distribution of HPV testing results. Table 5 describes the distribution of histology results for those individuals who underwent colposcopy.

Table 3. Characteristics by Cohort.

	Aptima HPV Assay	**Comparator cohort**
Age Group (years)		
25-29	17,919 (3.8%)	8,781 (4.6%)
30-39	149,981 (31.9%)	72,520 (38.2)
40-49	116,729 (24.8%)	44,788 (23.6%)
50-64	159,785 (34.0%)	57,491 (30.2%)
≥65	26,054 (5.5%)	6,473 (3.4%)
Cytology Results		
Unsatisfactory	5,666 (1.2%)	1,891 (1.0%)
NILM	429,002 (91.2%)	167,314 (88.0%)
ASC-US	27,807 (5.9%)	15,478 (8.1%)
>ASC-US	7,993 (1.7%)	5,370 (2.8%)

Table 4. HPV Positivity Overall and by Age for Each Cohort.

	Aptima HPV Assay	**Comparator cohort**
25-29	35.4% (6,341 / 17,919)	32.4% (2,848 / 8,781)

30-39	10.0% (14,927 / 149,981)	10.8% (7,850 / 72,520)
40-49	5.9% (6,928 / 116,729)	7.0% (3,135 / 44,788)
50-64	4.4% (7,071 / 159,785)	5.1% (2,937 / 57,491)
≥65	4.3% (1,118 / 26,054)	5.4% (348 / 6,473)
Overall	7.7% (36,385 / 470,468)	9.0% (17,118 / 190,053)

Table 5. HPV Assay Results by Disease Status for Each Cohort Among Women With Colposcopy Performed.

Age Group	Study Cohort	HPV Assay Result	Colposcopy No Biopsy	Normal	CIN 1	CIN 2	CIN 3	AIS	Cancer	Total
25-29	Aptima HPV Assay	Positive	260	1,352	1,116	356	217	7	2	3,310
		Negative	63	119	37	7	1	0	0	227
		Total	323	1,471	1,153	363	218	7	2	3,537
	Comparator cohort	Positive	152	398	663	114	150	3	3	1,483
		Negative	42	52	56	7	8	0	0	165
		Total	194	450	719	121	158	3	3	1,648
≥30	Aptima HPV Assay	Positive	682	5,390	2,665	890	1,004	48	32	10,711
		Negative	389	2,004	322	24	25	1	3	2,768
		Total	1071	7,394	2,987	914	1,029	49	35	13,479
	Comparator cohort	Positive	492	1,813	2,003	355	635	30	29	5,357
		Negative	263	941	226	14	21	0	7	1,472
		Total	755	2,754	2,229	369	656	30	36	6,829

AHPV = Aptima HPV
AIS = adenocarcinoma in situ
CIN2 = cervical intraepithelial neoplasia grade 2
CIN3 = cervical intraepithelial neoplasia grade 3

D. Safety and Effectiveness Results

1. Safety Results

   The Aptima HPV Assay involves sampling cells from the cervix using broom-type or cytobrush/spatula collection devices. Therefore the test, when used as part of HPV primary screening, presents no more safety hazard to an individual being tested than when used as part of triage of ASC-US cytology or co-testing.

2. Effectiveness Results

   Tables 6 and 7 show the results by age group for the detection of ≥CIN3 and ≥CIN2. For the detection of ≥CIN3 after adjustment by cytology, the ratios of clinical sensitivities between the Aptima HPV Assay and FDA-approved HPV Test in the 25-29 and ≥30 age groups were 0.9693 and 0.9957, respectively. For the detection of

≥CIN2 after adjusting for cytology, the ratios of clinical sensitivities between the Aptima HPV Assay and FDA-approved HPV test in the 25-29 and ≥30 age groups were 1.3277 and 1.1851, respectively.

Table 6. Performance of Aptima HPV Assay Compared to FDA-approved HPV test for Detection of ≥CIN3 and ≥CIN2 in Women 30 Years and Older.

	Parameter	Point Estimate	Lower Bound of 95% CI	Upper Bound of 95% CI
≥CIN3	Ratio of Sensitivities	0.9957	0.9162	1.0961
	Ratio of False Positive Rates	1.2105	1.1793	1.2418
≥CIN2	Ratio of Sensitivities	1.1851	1.1043	1.2754
	Ratio of False Positive Rates	1.1816	1.1454	1.2194

Table 7: Performance of Aptima HPV Assay Compared to FDA-approved HPV test for Detection of ≥CIN3 and ≥CIN2 in Women 25-29 Years Old.

	Parameter	Point Estimate	Lower Bound of 95% CI	Upper Bound of 95% CI
≥CIN3	Ratio of Sensitivities	0.9693	0.7011	1.2652
	Ratio of False Positive Rates	1.1191	1.0485	1.2501
≥CIN2	Ratio of Sensitivities	1.3277	1.0992	1.6138
	Ratio of False Positive Rates	1.0436	0.9669	1.1846

X. FINANCIAL DISCLOSURE

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The REACH study included ten investigators. None of the clinical investigators had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Microbiology Panel, an FDA advisory committee, for review and recommendation because this is the same assay using similar technology that has been reviewed by this panel.

XII. CONCLUSIONS DRAWN FROM CLINICAL STUDIES

A. Effectiveness Conclusions

The effectiveness of the device is based on data collected in the REACH study. The sensitivity of the Aptima HPV Assay for primary screening was demonstrated to be comparable to the FDA-approved HPV test for detection of ≥CIN2 and ≥CIN3.

B. Safety Conclusions

The risks of the device are based on data collected in the REACH study. The ratio of false positive rates between the candidate device and the FDA-approved HPV test demonstrated a higher likelihood of false positives with use of the Aptima HPV Assay in primary screening. Risks of a false positive test include improper patient management, including referral to colposcopy for further evaluation for possible pre-cancerous or cancerous cervical lesions. Colposcopies are invasive procedures that can be associated with substantial patient inconvenience, discomfort, and pain. It is anticipated that some of the risks associated with colposcopy may be mitigated by the fact that biopsies would not be performed unless abnormal lesions are observed on examination, in which case the colposcopy may have been warranted. Overall, colposcopy is a generally safe and well-tolerated procedure with rare complications (i.e. infection, bleeding).

The risks of false positives as described above is acceptable given the magnitude of clinical benefits anticipated with the device, including comparable sensitivity and improved risk stratification supporting patient management.

C. Benefit-Risk Determination

The probable benefits of the device are based on data collected in clinical studies to support PMA approval as described above. The probable benefits of the assay are the identification of individuals with potentially clinically significant infection with high-risk HPV genotypes that puts them at risk for the development of cervical pre-cancer or cancer. Expanding Indications for Use of this assay to include HPV primary screening can simplify the cervical cancer screening process, through which clinicians determine the risk of cervical pre-cancer or cancer for individual patients and make management recommendations including the need for colposcopy or treatment.

The probable risks of the device are failure to operate the device correctly, failure to interpret results correctly or risk of false results. These risks can be mitigated through product labeling including warnings/limitations, risk analysis and documentation, and general controls, specifically for individuals ages 30 and older. For individuals 30 years and older, the performance of the Aptima HPV Assay for primary screening was demonstrated to be comparable to the FDA-approved HPV test for detection of cervical disease. Among individuals 25 to 29 years old, the performance of the

Aptima HPV Assay for primary screening also was shown to be comparable to the FDA-approved HPV test for detection of CIN2+ and CIN3+. However, due to uncertainty around diagnostic performance of the Aptima HPV Assay for individuals 25 to 29 years old because of potential bias in clinical study design, a post-approval study will be conducted by the manufacturer to confirm the performance of the Aptima HPV Assay observed in this age group specifically. Overall, the observed performance in the original clinical study is sufficient to address the probable risks of the Aptima HPV Assay.

Considering the available information above and product labeling, , along with the planned post-approval study to confirm the diagnostic performance of the device in the 25-29 years old population, the benefits outweigh the risks for the proposed assay for the entire IU population.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the Indications for Use.

XIII. CDRH DECISION

CDRH issued an approval order on February 3, 2026. The final clinical conditions of approval cited in the approval order are described below.

You must provide clinical data evaluating the clinical performance of the Aptima HPV Assay compared to a comparator test approved for primary screening in women aged 25-29 years from CERVIVA Primary Screening Study, confirming the safety and effectiveness of the device in this specific age group. The data includes approximately 1,800 women aged 25-29 years and provides the ratio of clinical sensitivity and false positive rates for detection of CIN2+ and CIN3+.

Separate PAS Progress Reports must be submitted every six (6) months for the first year and annually thereafter, from the date of the PMA approval letter, unless otherwise specified by FDA. The Final PAS Report should be submitted no later than one year from the date of the PMA approval letter, unless otherwise specified by FDA.

Each PAS report should be submitted to the address below identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified above and bearing the applicable PMA reference number.

Be advised that failure to comply with any post-approval requirement constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 814.46(a)(2).

The applicant’s manufacturing facility was inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820), which was in effect at the time

of the inspection. As of February 2, 2026, the revised part 820, referred to as the Quality Management System Regulation (QMSR), is effective.

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.