

Individuals using assistive technology may not be able to fully access the information contained in this document. For assistance, please call 1(800) 638-2041 or (301) 796-7100 or send an email to CDRH's [Division of Industry and Consumer Education \(DICE\)](#). Please include “**508 Accommodation**” and the **title of the document** in the subject line of your e-mail.

FDA SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

OFFICE OF PRODUCT EVALUATION AND QUALITY TEMPLATE

Note to FDA SSED authors: The Summary of Safety and Effectiveness (SSED) is a document mandated by the Food, Drug and Cosmetic Act subparagraph 520(h)(1)(A) to be publicly available upon issuance of an approval order of a premarket approval application (PMA) at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>. The SSED is applicable for all original PMAs and Panel-Track Supplements.

The SSED is an FDA document intended to present a reasoned, objective, and balanced summary of the scientific evidence, both positive and negative, that served as the basis of the decision to approve or deny the PMA. For a PMA to be approved, probable benefits must be determined to outweigh the probable risks of the device for the labeled indication, and there must be a reasonable assurance of safety and effectiveness, based on nonclinical and clinical studies, as documented in the SSED. There can be no claims in the SSED that are unsubstantiated by the clinical results of the PMA clinical study(ies).

NOTE: This template contains the essential elements that should, at minimum, be included in the SSED (e.g., standard content headings, Times Roman 12 font, etc.). Additional instructions or examples of what should be included under each topic heading are indicated by italicized text. This document is intended to provide general recommendations to OPEQ reviewers for writing the SSED. However, there will be exceptions, as well as devices that will require additional sections. Consult your Assistant Director/Branch Chief or your PMA Staff representative if you have questions.

If the PMA applicant provides a draft SSED: No matter what format that the applicant provides the initial SSED when the original PMA or panel-track supplement is submitted, a reviewer is expected to reformat the SSED to be consistent with the format below. The PMA Staff will return SSEDs that do not follow this format. FDA's intention is to provide an SSED that is consistent in format and content in order to provide a level playing field for Industry.

If you include any pictures or figures, make sure to include alternative text for 508 compliance [Right click on the picture/figure -> Format -> click on the Web Tab -> Enter an alternative text description]

Red text represents instructions for the reviewers and should be deleted in the SSED

Black text represents text, or parts of text, that would appear in the final SSED

The next page is the first page of your SSED. Delete all of the above text, including headers, after reading

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:

Device Trade Name:

Device Procode:

Applicant's Name and Address:

Date(s) of Panel Recommendation: *[If no panel recommendation, state:]* None

Premarket Approval Application (PMA) Number:

Date of FDA Notice of Approval:

Priority Review: *[If the application was granted priority review, **PRIOR TO DECEMBER 13, 2016, state:]** Granted priority review status on [date] because [insert the reason specified in the letter granting priority review]. *Delete listing if Priority Review was not granted.**

Breakthrough Device: *[If the application was granted breakthrough device status, state:]* Granted breakthrough device status on [date] because [insert the reason specified in the letter granting breakthrough]. *Delete this paragraph if Breakthrough Status was not granted.*

Safer Technologies Program (SteP) for Medical Devices: *[If the application was granted breakthrough device status, state:]* Granted SteP breakthrough status on [date] because [insert the reason specified in the letter granting breakthrough]. *Delete this paragraph if Breakthrough Status was not granted.*

For panel-track supplements only, include a paragraph immediately before the indication for use section to identify the previous approved indications for use and date of approval(s), and indicate that the SSED supporting the original indication is available on the CDRH website. Often the preclinical data to support a panel-track supplement are the same as the original PMA data and can be incorporated by reference. If this is the case, instead of repeating the test results in the current document, you can refer the reader to a previous SSED for the information.

For example: The original PMA (PMA #) was approved on [Date of Approval] and is indicated for [specify indication for use]. The SSED to support the indication is available on the CDRH website and is incorporated by reference here. The current supplement was submitted to expand the indication for the [device].

II. **INDICATIONS FOR USE**

The (device) is indicated for use in *(the treatment, prevention, diagnosis, relief and/or aid/adjunct to mode of therapy/diagnosis) of (disease, condition, manifestation of disease/condition, symptoms associated with disease/condition). (Where appropriate, additional specifics can be added, such as temporary duration of effect, limitations of usefulness, selected subgroup of a population with a disease/condition/symptom, conditions to be met before device is used, etc.).*

This statement identifies the target population in which the device has been clinically evaluated, with valid scientific evidence that demonstrates reasonable assurance of safety and effectiveness, and must be stated exactly as in the final labeling and approval order. This section should include all the parameters that define the appropriate populations for which the device is used.

III. **CONTRAINDICATIONS**

(List exactly as in the final draft labeling)

[Care should be taken to ensure that the contraindications meet the definition of contraindications. That is, the device can never be used under the conditions listed in this section. Clinical data to establish a contraindication for the device need not occur for it to appear in the labeling.]

The contraindications section should describe situations in which the device should not be used because the risk of use clearly outweighs any probable benefit. Examples that may, but not always, contraindicate the use of a device include:

- Hypersensitivity to an ingredient of a permanently implanted device.
- Substantial risk of being harmed because of sex, gender, age, race, ethnicity, concomitant therapy, disease state or other condition.
- Continued use in the face of an unacceptably hazardous adverse reaction.

Known hazards rather than theoretical possibilities are to be listed, e.g., if hypersensitivity to an ingredient in the device has not been demonstrated, it should not be listed as a contraindication. The "Contraindications" section shall immediately follow the "Indications for Use" section of the labeling. If no contraindications are known, this section of the labeling should state "There are no known contraindications."

IV. **WARNINGS AND PRECAUTIONS**

The warnings and precautions can be found in the [device trade name] labeling.

V. DEVICE DESCRIPTION

The [device trade name] is a...

[Provide the full device name, with optional abbreviated name. Briefly describe what the device is and what it does. List and briefly describe the key components and subsystems, and refer to the Operator's/Physician's Manual for additional details. It is helpful to add a diagram, photo, or something visual either as a separate entity or shown in place in the appropriate body part. The intended use (if appropriate for the particular device) should be described as a statement of what the device is supposed to do.]

If the proposed device contains functions not regulated as a medical device, include the following paragraph. See the [Multiple Function Device Products: Policy and Considerations – FDA Guidance Document](#) for more information.]

[start multi-function paragraph] This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review. *[/end multi-function paragraph]*

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of [*specify disease or condition(s)*]. [*List/discuss all other approved surgical and medical alternatives*]. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

**All conventional procedures and practices used for the desired indication should be described, both medical and surgical, as well as legally marketed devices. Do not include investigational uses.*

VII. MARKETING HISTORY

If the device has been marketed outside the U.S., then state this and list the countries in which the device has been marketed. Also, state whether the device has or has not been withdrawn from marketing for any reason related to its safety or effectiveness.

If there is no marketing history, then state the following: “The [Device Trade Name] has not been marketed in the United States or any foreign country.”

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device. *[List all potential adverse effects. Adverse events listed should be those that might reasonably occur if a large enough cohort of subject were treated with the device, but should not be theoretical in nature. Include adverse outcomes known from published or unpublished sources outside of the PMA clinical studies, both for the current PMA device, as well as for other devices in the same category, whether approved or not. Data sources for the potential adverse effects could come from approved device labeling, published scientific literature, international marketing experience, etc. Frequency data from valid scientific published literature can be provided when determined necessary for practitioner/patient decision-making. If appropriate and clinically significant, report adverse events by subgroups of sex, gender, age, race, and ethnicity.]*

For the specific adverse events that occurred in the clinical study(ies), please see Section X below.

IX. SUMMARY OF NON-CLINICAL STUDIES

Briefly describe each bench and animal test performed, either in text or tabular form. Identify the test method, the purpose of the test, how it was conducted, the acceptance (pass/fail) criteria (do not include trade secret information), and the test results. Include only one test per paragraph. The testing performed for each key component and subsystem of the device should be described. It can be helpful to specify when the test was conducted in accordance with a published standard or FDA guidance document; note that not all standards include pass/fail criteria, so this information should be provided.

Test	Purpose	Acceptance Criteria	Results

A. Laboratory Studies

B. Animal Studies

C. Additional Studies

EXAMPLE (Note: purpose of test can be in table or described in text):

Test	Acceptance Criteria	Results	Analysis Type
Electrical Testing			
DC Resistance	Tip Circuit (78 cm lead) = $35\Omega \pm 10\Omega$	Passed	Variables

	Ring Circuit (78 cm lead) = $35\Omega \pm 10\Omega$		
IS-I Connector Leakage/AC Impedance Test of Unipolar Leads	Impedance > 50 kOhms	Passed	Attribute
Sterilization			
Sterilization	100% EtO sterilization process is used. It is considered an overkill sterilization cycle and is performed in accordance with accepted standards (state complete name of standard). Devices must have a sterility assurance of at least 10^{-6} . Sterilization validation was performed by comparison to "worst case" devices.	Passed	20 partial leads (Model xxxx). Proximal and distal ends of leads were cut and capped to create a worst case condition.

X. SUMMARY OF PRIMARY CLINICAL STUDY(IES)

Often there is more than one clinical study (feasibility/pilot, pivotal, supporting studies) that investigates the various aspects of the safety and effectiveness of a device. The majority of the discussion should center on the study that supplied supportive data for the final determination of safety and effectiveness; however, this section should include subsections with pertinent information for each study (although perhaps in less detail for a pilot/feasibility study) that was central to your decision making process. If there are multiple studies, it may be helpful to provide a table with all of the studies and their major characteristics (purpose, control arm, primary endpoint, etc.) in the front of this section, with narrative sections explaining the results as supportive of FDA’s decisions following it.

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of [procedure] with [device] for [indication] in the US [state additional countries, if applicable] under IDE # [specify number]. Data from this clinical study were the basis for the PMA approval decision. (If additional data was pooled with the PMA clinical study, or additional foreign studies were used to support the PMA, they should be described briefly.) A summary of the clinical study is presented below.

This clinical section of the SSED should provide a condensed summary of the clinical study, including both positive and negative outcomes.

A. Study Design

Patients were treated between [date] and [date]. The database for this [PMA/Panel Track Supplement] reflected data collected through [date] and included ### patients. There were ### investigational sites.

The study was a [*include all that apply, such as: prospective, multi-center, one/two-arm, cohort study, randomized, (un)masked, etc.*] clinical study. Major design characteristics should be identified, including level of blinding (e.g., double-blinded, partially-blinded, open-label), type of controls, duration of study, method of allocation to treatment groups (e.g., randomization), and treatment arms. Briefly describe the statistical analysis plan (e.g., Frequentist, Bayesian, Adaptive), including a description of the statistical method, hypothesis, sample size justification, assumptions, and statistical analysis plan.

Include a brief description of any core laboratory use, independent evaluators, and/or Data Safety Monitoring Board (DSMB)/Independent Data Monitoring Committee (IDMC).

The control group was [*include appropriate description of the control group, such as: the preoperative state, historical control group (explain), active alternative treatment outcome (explain), or placebo*]. If an active control, state that the control treatment was “a legally marketed alternative with similar indications for use.”

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the [name] study was limited to patients who met the following inclusion criteria [*include a summary of the pertinent criteria*].

Patients were not permitted to enroll in the [name] study if they met any of the following exclusion criteria: (*include a summary of pertinent criteria*).

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at (*list hours/days/months with protocol time windows of all scheduled exams*) postoperatively. *Include a discussion of subgroup populations that received additional types of evaluations that not all the patients may have had.*

Preoperatively, (*list all evaluations performed in relation to the index procedure*). Postoperatively, the objective parameters measured during the study included (*list all assessments (the tools to assess the endpoints) performed and specify if only at specific visits. A detailed chart may be effective/efficient here*). Adverse events and complications were recorded at all visits.

The key timepoints are shown below in the tables summarizing safety and effectiveness.

3. Clinical Endpoints

With regards to safety, (*Include those that are clinically meaningful, and contribute to the final decision that was made*).

With regards to effectiveness, (*Include those that are clinically meaningful and contribute to the final decision that was made*).

With regard to success/failure criteria, *(This should include a definition of individual patient success, as well as for the study overall. Often the latter is stated as a statistical hypothesis or as a proportional comparison to the control).*

B. Accountability of PMA Cohort

At the time of database lock, of [add number] patients enrolled in the PMA study, %(n) patients are available for analysis at the completion of the study, the xx month/year post-operative visit *(final visit evaluated for safety and effectiveness as the basis for the PMA submission).*

Include an accountability summary table or patient accountability tree. This section should clearly define which set of patients is what analysis cohort (e.g., the intent-to-treat cohort, the per protocol cohort, evaluable cohort).

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are [typical/atypical] for a [type] study performed in the US.

Report study demographics in terms of the proportion of enrolled and completed by subgroup by including a table. Discuss whether the proportions enrolled are consistent with the sex, gender, age, racial and ethnic prevalence of disease in the US. The enrollment of other demographic subgroups may also be reported and discussed as appropriate (e.g., geographic region, primary language spoken, socioeconomic status, sexual orientation, etc.). If proportions enrolled are substantially different than prevalence of disease by these subgroups, include a rationale that these results apply to all patients who might be treated by the device.

Also include a table showing the distribution of baseline parameters for clinically relevant variables important for understanding the safety and treatment effect, and other population characteristics that have important implications for the extent to which the PMA study results can be generalized.

D. Safety and Effectiveness Results

Statistical significance (p)-values should be provided for primary safety and effectiveness outcomes for studies that used such statistical methods; posterior probability distributions should be provided for studies that used Bayesian statistical methods. Discuss the appropriate wording and presentation, if any, for p-values and statistics for secondary endpoints with the team statistician.

1. Safety Results

The analysis of safety was based on the [list type] cohort of [add number] patients/procedures, etc. available for the [add number] month evaluation. The

key safety outcomes for this study are presented below in Tables **xx** to **xx**. Adverse effects are reported in Tables **xx** to **xx**.

Adverse effects that occurred in the PMA clinical study:

List all adverse effects observed during the PMA clinical study, with incidence rate and number, in descending order of clinical importance, as determined by their severity and/or incidence. It is helpful to present these data in tabular form with a comparative column listing the adverse events that occurred in the control treatment group.

Specifics of device or procedure related events should be further discussed in the clinical studies section. You may choose a cut-off such as “events occurring at a rate >1% or >5%.” However, for novel devices with small studies, including adaptive and bayesian designs, consider the clinical importance and device relatedness of low rates of occurrence in a larger proportion of the general population with the disease being treated. Consider whether the lack of effectiveness as manifested by worsening of the original condition should or should not be counted as an adverse event. This should be evaluated on a case by case basis and may be condition specific.

Include all tables deemed important in the determination of device safety. A short narrative that describes significant findings should be associated with each table. A time course of the occurrence of adverse events as compared to the control treatment is recommended in relation to the initial treatment.

Include any additional observations by the clinical reviewer.

If adverse events led to any device design modifications during the PMA clinical study, they should be described briefly. Identify the cause of any device failures and the number of occurrences.

2. **Effectiveness Results**

The analysis of effectiveness was based on the [add number] evaluable patients at the [add number]-month time point. Key effectiveness outcomes are presented in Tables **xx** to **xx**.

Provide FDA’s clinical assessment as to the acceptability of these rates.

Include all tables on all cohorts deemed important in the determination of device effectiveness.

3. **Subgroup Analyses**

If subgroup analyses are provided state the following:

The following baseline characteristics were evaluated for potential association with safety and effectiveness outcomes: *(e.g., sex, gender, age, race, ethnicity,*

comorbidities, site, geographic location, and any other relevant characteristics). (Describe associations found with outcomes.)

Include appropriate subgroup analyses for both safety and effectiveness outcomes and specify the following:

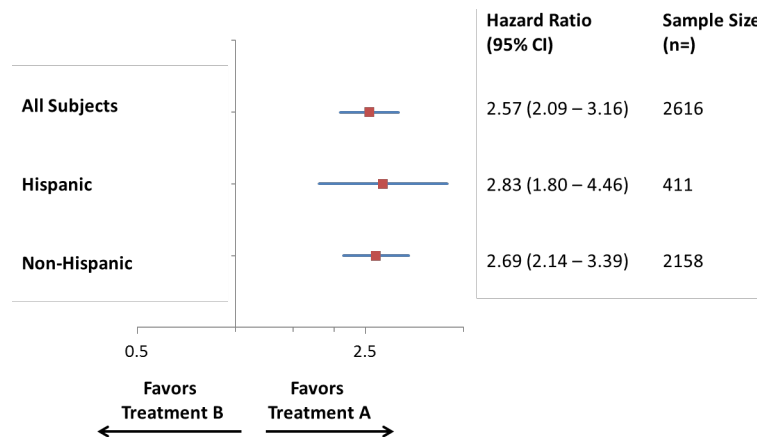
The study [was/was not] specifically powered for [sex-, gender-, age-, race-, ethnicity-, or any other relevant characteristic- specific] subgroups.

If no subgroup analysis was provided for certain characteristics, state the following: No analyses were performed for [sex-, gender-, age-, race-, ethnicity-, or any other relevant characteristic- specific] subgroups.

For further information please see [Evaluation of Sex-Specific Data in Medical Device Clinical Studies and Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies and Collection of Race and Ethnicity Data in Clinical Trials](#) guidance documents.

You may choose to use a table or forest plot as potential options for reporting outcomes. See examples below. Use similar table or plot to reflect the out of US data. If the examples shown below are not relevant to the device study design, they may be adapted or removed.

Parameter	Category	Endpoint 1			Endpoint 2		
		Test	Control	p-value (if pre-specified)	Test	Control	p-value (if pre-specified)
Sex	<i>Male</i>						
	<i>Female</i>						
Gender	<i>Man</i>						
	<i>Woman</i>						
	<i>Non-binary/other</i>						
Age	<i>List all relevant categories</i>						
Race	<i>American Indian or Alaska Native</i>						
	<i>Asian</i>						
	<i>Black or African American</i>						
	<i>Native Hawaiian or Other Pacific Islander</i>						
	<i>White</i>						
	<i>Other</i>						
	<i>Multiracial</i>						
	<i>Not reported by subject</i>						
Ethnicity	<i>Hispanic or Latino</i>						
	<i>Not Hispanic or Latino</i>						
	<i>Not reported by subject</i>						



Sample table of endpoints 1 and 2 by relevant specific subgroups, and forest plot of hazard ratio by ethnicity-specific subgroups

4. Pediatric Extrapolation

Implementation of FDA Guidance entitled “Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices.”

As a reference, Table 1 includes the age ranges of the pediatric sub-populations

Table 1. Age Ranges of Pediatric Sub-population

<i>Pediatric Subgroup</i>	<i>Approximate Age Range</i>
<i>Newborn (neonate)</i>	<i>from birth to 1 month of age</i>
<i>Infant</i>	<i>greater than 1 month to 2 years of age</i>
<i>Child</i>	<i>greater than 2 to 12 years of age</i>
<i>Adolescent</i>	<i>greater than 12 through 21 years of age</i>

Please NOTE: This section is only relevant to regulatory submission in which data (in the adult population or another pediatric sub-population) was leveraged to support approval of a pediatric patient population or sub-population. This section does not apply when pediatric data is generated to support the studied patient population.

Pick OPTION 1 or OPTION 2:

OPTION 1: If data/information was leveraged for (a) pediatric indication(s) in the submission or considered during review, state:

In this premarket application, existing clinical data was leveraged to support the ***[OPTION: reasonable assurance of safety and effectiveness OR safety OR effectiveness]*** of the proposed device in ***[OPTION: the pediatric sub-population of {list sub-population} OR pediatric patients]***.

Instructions: Provide a summary of the leveraged data used to support the use of the device in a pediatric population or sub-population. If the specific details about the leveraged data are included elsewhere in the SSED, the specific section/sub-section of the document can be referenced here. Consider including information to explain the following:

- *A brief summary (1-2 sentences) of the data that was extrapolation.*
- *To what extent was data leveraged? Full or partial extrapolation?*
- *Why is extrapolation of the data appropriate for this device and indications for use?*

OPTION 2: *If data/information was not leveraged to support a pediatric indication, include the following statement:*

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

XI. FINANCIAL DISCLOSURE

(This section should briefly summarize our evaluation of the clinical investigator financial disclosure information submitted in accordance with 21 CFR 54. If our approval decision is based on data provided from more than one pivotal study, the findings from each study should be discussed separately. Please refer to the guidance document, "[Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators](#)" for additional information).

[OPTION 1 – NO DISCLOSABLE FINANCIAL ARRANGEMENTS]

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 pivotal clinical study included [add number] 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. [END OF OPTION 1]

[OPTION 2 – DISCLOSABLE FINANCIAL ARRANGEMENTS: NO EFFECT ON RELIABILITY OF DATA]

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 pivotal clinical study included [add number] investigators of which [# of investigators/none] were full-time or part-time employees of the sponsor and [# of investigators/none] had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: [# of investigators]
- Significant payment of other sorts: [# of investigators]
- Proprietary interest in the product tested held by the investigator: [# of investigators]
- Significant equity interest held by investigator in sponsor of covered study: [# of investigators]

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data. [END OF OPTION 2]

[OPTION 3 – DISCLOSABLE FINANCIAL ARRANGEMENT: EFFECT ON RELIABILITY OF DATA]

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 pivotal clinical study included [# of investigators] of which [# of investigators/none] were full-time or part-time employees of the sponsor and [# of investigators] had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: [# of investigators]
- Significant payment of other sorts: [# of investigators]
- Proprietary interest in the product tested held by the investigator: [# of investigators]
- Significant equity interest held by investigator in sponsor of covered study: [# of investigators]

Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. FDA determined the information provided did raise questions about the reliability of the data. The following additional actions were taken and deemed necessary to ensure the reliability of the data (21 CFR 54.5(c)). [Describe additional steps taken which may include: 1) Initiating agency audits of the data derived from the clinical investigator(s) in question; 2) Requesting that the applicant submit further analyses of data (e.g., to evaluate the effect of the clinical investigator's data on the overall study outcome); 3) Requesting that the applicant conduct additional independent studies to confirm the results of the questioned study; 4) Eliminating a specific site(s) from analysis] [Conclusions] [END OF OPTION 3]

XII. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

OPTIONAL SECTION

This section should describe results for other information considered such as Continued Access, European, or other Outside-the-US (OUS) clinical data, as well as potentially relevant subsets of the study cohort of potential interest to physicians and/or patients (e.g., pediatric, diabetic or other disease/condition of interest, and any other relevant characteristics). Include relevant covariate analyses, if performed, and why they were done.

This section may also include information from literature used to support PMA approval.

This section may also include information regarding protocol deviations and investigator or other biases that may have been identified and whether they affected outcomes or not.

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

[OPTION – Device did not go to Panel]

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 **[Name of Panel]**, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.]

[OPTION – Panel Meeting held]

A. Panel Meeting Recommendation

At an advisory meeting held on **[date]**, the **[Name of Panel]** Panel voted **[VOTE TALLY]** that there **[is/is not]** reasonable assurance the device is safe, **[VOTE TALLY]** that there **[is/is not]** reasonable assurance that the device is effective, and **[VOTE TALLY]** that the benefits of the device **[do/do not]** outweigh the risks in patients who meet the criteria specified in the proposed indication. *[Include the specific panel webpage link to the panel meeting summary.] [If conditions of approval were discussed, list the conditions.]*

B. FDA's Post-Panel Action

[OPTION]

If there are some recommendations FDA chose not to accept from the Panel, this section should explain why. In addition, if FDA is going against a Panel recommendation for approval or disapproval, this section should include a rationale of our decision. Describe any information submitted by the applicant in response to outstanding issues, and whether the response was found acceptable. Include the resolution of any outstanding issues raised by the Panel or by FDA, as appropriate. State whether all the Panel recommendations are being followed/implemented or not.

[END OPTION]

XIV. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

Summarize the effectiveness outcomes of the PMA clinical study(ies) and clinical conclusions, including determination of clinical significance of endpoint outcomes and evidence that outcomes met acceptance criteria for a significant portion of the target patient population. If applicable, your conclusions should consider the panel deliberations and conclusions and FDA's post-panel actions. Consider whether any meaningful outcome differences by sex, gender, age, race, ethnicity, or any other relevant characteristics are impacting the effectiveness of the device (see [Evaluation of Sex-Specific Data in Medical Device Clinical Studies and Evaluation, Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies](#) and [Collection of Race and Ethnicity Data in Clinical Trials](#) guidance documents).

B. Safety Conclusions

The risks of the device are based on [nonclinical laboratory and/or animal studies (as applicable) as well as] data collected in a clinical study(ies) conducted to support PMA approval as described above. *Summarize the risks associated with use of the device to include the following: number, severity and types of harmful events (device-related serious adverse events, device-related non-serious adverse events, procedure-related or indirect harms), probability of a harmful event, duration of harmful events, risk of false-positive or false-negative for diagnostics, etc.. Discuss the safety outcomes of the PMA clinical study(ies) and clinical conclusions, including determination of clinical significance of endpoint outcomes and evidence that outcomes met acceptance criteria. Consider whether any meaningful outcome differences by sex, gender, age, race, ethnicity, or any other relevant characteristics are impacting the safety of the device (see [Evaluation of Sex-Specific Data in Medical Device Clinical Studies and Evaluation, Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies](#) and [Collection of Race and Ethnicity Data in Clinical Trials](#) guidance documents).*

C. Benefit-Risk Determination

The probable benefits of the device are also based on data collected in a clinical study(ies) conducted to support PMA approval as described above. *Summarize the benefits of the devices, to include the following: type of benefit(s), magnitude of the benefit(s), probability of the patient experiencing a benefit, and duration of effect(s).*

The probable risks of the device are also based on data collected in a clinical study(ies) conducted to support PMA approval as described above. *Summarize the risks of the devices, to include the following: severity, types and rates of device-related adverse events, probability and duration of device-related adverse events, as well as procedure-related complications.*

Additional factors to be considered in determining probable risks and benefits for the [device trade name] device included: *Summarize the following additional benefit/risk factors, including: uncertainty (quality of the study design, quality of the conduct of the study, robustness of the analysis of the study results, generalizability of results), characterization of the disease, patient tolerance for risk (disease severity, disease chronicity), availability of alternative treatments or diagnostics, patient-centric assessment, risk mitigation, and novelty of technology. Consider whether any meaningful outcome differences by sex, gender, age, race, ethnicity, or any other relevant characteristics are impacting the benefit-risk profile of the device (see [Evaluation of Sex-Specific Data in Medical Device Clinical Studies and Evaluation, Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies](#) and [Collection of Race and Ethnicity Data in Clinical Trials](#) guidance documents).*

1. Patient Perspective

Pick OPTION 1 or OPTION 2:

[OPTION 1] If patient perspectives (which may also include patient experience data) were provided in the submission or considered during review, state:

Patient perspectives considered during the review included:

Relevant patient perspectives could be based on attributes of the device type and/or patient population, or the specific device under review. Where available, include patient perspectives which may also include patient experience data from the benefit-risk assessment worksheet or elsewhere in the submission. Examples include but are not limited to:

- information on how a patient feels or functions (patient reported outcome measures (PRO))*
- information that captures relative desirability or acceptability of outcomes or other attributes that differ among alternative health interventions to patients, the value patients place on the treatment or diagnosis;*
- patient tolerance for risk to achieve benefit (given disease severity, chronicity, etc.);*
- how well are patients able to understand the benefits and risks;*
- information voiced by multiple patients at patient listening sessions or other relevant patient engagement events; or*
- any other relevant patient-centric assessments.*

[END OPTION 1]

[OPTION 2] If patient perspectives (which may include patient experience data) were not provided in the submission or not considered during review, include the following statement:

This submission either did not include specific information on patient perspectives or the information did not serve as part of the basis of the decision to approve or deny the PMA for this device.

[END OPTION 2]

In conclusion, given the available information above, the data support that for *[the indication for use of the device]* the probable benefits outweigh the probable risks. *If applicable, your conclusions should consider the panel deliberations and conclusions and FDA's post-panel actions.*

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. *Include a discussion of the overall safety and effectiveness analysis (i.e., describe how the benefits of using the device outweigh the risks and how the data support that a significant portion of the patient population will achieve clinically significant results). If applicable, your conclusions should consider the panel deliberations and conclusions and FDA's post-panel actions.*

XV. CDRH DECISION

CDRH issued an approval order on [date of approval order]. [OPTION: if there are clinical conditions of approval, state the following: The final clinical conditions of approval cited in the approval order are described below.

Add the clinical conditions of approval – change to 3rd person.[END OPTION]

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XVI. 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.

XVII. REFERENCES

(Only include references cited in the SSED and determined appropriate for inclusion.)