**Performance Testing**

1 Was Bench Testing used in order to support this submission?

2 Was Animal Testing used in order to support this submission?

3 Was Clinical Testing used in order to support this submission?

4 Provide a brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. If any guidance documents or FDA recognized consensus standards were used/referenced for testing, cite these here.

*【See 21 CFR 807.92(b) for the regulatory requirements regarding this question.*

*Resources:*

*21 CFR 807.92(b)*

*<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=807.92>*

*】*

5 Provide a summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. Refer to the help text for a list of the details we recommend be included regarding the subjects and clinical evidence. If no clinical data were necessary, please type "Not Applicable." (There should not be any patient identifier information in the summary.)

*【See 21 CFR 807.92(b) for the regulatory requirements regarding this question.*

*Be sure to include a summary of baseline demographic information and where appropriate, subgroup analyses for sex, gender, age, race, and ethnicity of the subjects.*

*Resources:*

*21 CFR 807.92(b)*

*<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=807.92>*

*】*

6 State the conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified above.

*【See 21 CFR 807.92(b) for the regulatory requirements regarding this question.*

*Resources:*

*21 CFR 807.92(b)*

*<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=807.92> 】*

**7 Bench Testing**

*【Please see the FDA Guidance “Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions” to ensure you have properly documented and tested your device.*

*Resources:*

*Guidancce: “Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions”】*

7.1 Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.

7.2 Please attach documentation that includes details of the bench testing performed with your device (test report, characterization, etc). A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test support this submission.

*【Contains information about any tests/studies/evidences conducted to support the submission. This should include:*

* *A summary of the non-clinical evidence that falls within this category*
* *A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)*
* *Discussion to support why the evidence presented is sufficient*

*Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device. In addition, the sponsor/applicant should consult any existing regional regulatory guidance related to where these attachments should be included.*

*Physical and Mechanical Characterization: Evidence that support the physical or mechanical properties of the subject device is to be included in this section. If applicable, this should include particulate testing from wear or device coatings.*

*Chemical/Material Characterization: Tests that describe the chemical or structural composition of the device and its components are to be included in this section.*

*Radiation Safety: Studies supporting radiation safety, where the device emits ionizing and/or non-ionizing radiation or where the device is exposed to radiation are to be included in this section. This includes bench tests ensuring safety and performance to support the MRI safety labelling of the device.*

*Non-Material-Mediated Pyrogenicity: Studies to support pyrogenicity evaluation of final release, such as endotoxin levels, are to be included in this section.*

*Safety of Materials of Biological Origin (human/animal): Evaluations performed to demonstrate the safety of materials of biological origin (e.g. animal sourced, human sourced material) are to be included in this section.*

*Usability/Human Factors: Studies specifically assessing the instructions and/or device design in terms of impact of human behaviour, abilities, limitations, and other characteristics on the ability of the device to perform as intended should be included here.*

*】*

**8 Animal Testing**

8.1 Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.

8.2 Please attach documentation that includes details of the animal testing performed with your device. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test support this submission.

8.3 Please include a study protocol which includes all elements as outlined in 21 CFR

58.120.

*【Please see 21 CFR 58.120 for more information.*

*Resources:*

*21 CFR 58.120*

*<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=58.120>*

*】*

8.4 Please include a final study report which includes all elements as outlined in 21

CFR 58.185.

*【Please see 21 CFR 58.185 for more information.*

*Resources:*

*21 CFR 58.185*

*<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=58.185>*

*】*

8.5 Please provide a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, please explain why the noncompliance would not impact the validity of the study data provided to support this submission.

*【Please see 21 CFR 58 for more information.*

*Resources:*

*21 CFR 58:*

*<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=58>*

*】*

**9 Clinical Testing**

9.1 Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.

9.2 Please attach documentation that includes details of the clinical testing performed with your device. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test support this submission. Choose the attachment type in the dropdown for each attachment.

*【Other clinical Evidence: This is documentation that may be important to the submission but that does not fit in any of the other documentation types below.*

*Overall Clinical Evidence Summary: This is a brief summary of the available clinical evidence being presented in support of the submission. The document should list the evidence presented, its characteristics (RCT, case study, literature review, postmarket data from another jurisdiction or from a marketed device) and provide a discussion of how this is considered sufficient to support request for marketing for the requested indications. A tabular listing of clinical studies may be included.*

* *If any of the study devices differ from the devices to be marketed, including competitors devices, include a description of these differences and their impact on the validity of the evidence in terms of support for the application. This may include a comparison of the clinical, technical and biological characteristics of the two devices, with a critical analysis demonstrating the devices to be similar to such an extent that there would be no clinically significant difference in safety or performance.*
* *Include a discussion of the clinical evidence considered for the device and support for their selection (i.e. what type of evidence was considered and why they were or were not used). Also include a discussion to support why the evidence presented is sufficient to support the application. Note: Human factors testing that include patients should be included in the Overall Clinical Evidence Summary.*

*Clinical Evaluation Report: This is a report reviewed and singed by an expert in the relevant field that contains an objective critical evaluation of all of the clinical data submitted in relation to the device. This should include a complete curriculum vitae, or similar documentation, to justify the choice of the clinical expert.*

*Clinical Trial Summary: A summary of: 1) The key characteristics of the study (e.g. title of study, investigators, sites, study period (date of enrollment/date of last completed), objectives, methods, number of patients, inclusion/exclusion criteria), 2) whether the data are sex-, gender-, age-, race-, and ethnicity- disaggregated; 3) Summary of the results of the analysis; and 4) Summary of conclusions related to the endpoints*

*Clinical Trial Report: The clinical study report should include elements such as the investigational plan/study protocol, protocol changes and deviations, description of patients, data quality assurance, and analysis/results.*

*Clinical Literature Review and Other Reasonable Known Information: This includes clinical literature review that critically reviews available information that is published, available, or reasonably known to the applicant/sponsor that describes safety and/or effectiveness of the device (both favourable and unfavourable). Provide a reproducible search protocol, selection/appraisal criteria, and legible copies of key articles, including translations, if applicable, to meet regulator language requirements.*

*Note: You should explicitly address any existing regional regulatory related to the clinical study and data provided here regarding the device.*

*】*

9.3 Patient-Reported Outcomes and Patient Preference Information

9.3.1 Does your clinical testing include patient-reported outcomes (PROs) or patient preference information (PPI)?

*【A Patient-Reported Outcome (PRO) is a measurement based on a report that comes directly from the patient (i.e., study subject) about the status of a patient’s health condition without amendment or interpretation of the patient’s response by a clinician or anyone else. A PRO can be measured by self-report or by interview provided that the interviewer records on the patient’s response. PROs may capture symptoms or function. A PRO instrument is typically a questionnaire, survey, or diary.*

*As appropriate, please include PRO questionnaire, dossier, and/or other supportive documents.*

*A guidance document is available to aid you in preparing a comprehensive submission. The document entitled “Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims” is available at the link below.*

*A Patient Preference Study or Patient Preference Information (PPI) is defined as qualitative or quantitative assessments of the relative desirability or acceptability to patients of specified alternatives or choices among outcomes or other attributes that differ among alternative health interventions.*

*As appropriate, please include the PPI survey, protocol, attribute table, and/or other supportive documents.*

*A guidance document is available to aid you in preparing a comprehensive submission. The document entitled “Patient Preference Information - Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling” is available at the link below.*

*Resource:*

*PRO Guidance*

*Guidance:“Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims”*

*PPI Guidance*

*Guidance:“Patient Preference Information – Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling”】*

9.4 Compliance with Good Clinical Practice for Supporting Clinical Investigations

9.4.1 Is one or more of the included clinical investigations intended to support this submission subject to the requirements governing FDA acceptance of data from clinical investigations? Click the Help Text button for more information.

*【FDA requirements for acceptance of clinical data from investigations is described in 83 FR 7366 (Final Rule titled “Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices”). Clinical investigations are subject to the requirements as described in the final rule that meet the following conditions:*

* *Research involving one or more human subjects to determine the safety or effectiveness of a device (21 CFR 812.3(h)).*
* *First subject signed informed consent documents on or after February 21, 2019(83 FR 7366).*

*Choose “Yes” if both of these conditions are true for one or more clinical investigations in the submission, or choose “No” otherwise.*

*For more information, refer to the “Acceptance of Clinical Data to Support Medical Device Applications and Submissions FAQ” Guidance. This guidance document is intended to help sponsors and applications understand and comply with the new requirements of 21 CFR parts 807, 812 and 814.*

*Resources*

*Guidance: “Acceptance of Clinical Data to Support Medical Device Applications and Submissions Frequently Asked Questions”*

*】*

10 Guidance and Special Controls Adherence