510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
QUICK REVIEW DECISION MEMO

Reviewer:

510(k) #:
510(k) Holder:
Device Name:

Regulation Number:
Regulation Name:
Regulatory Class:
Product Code:

ASSESSMENT SUMMARY

The initial assessment should be completed within one week of being assigned a new Traditional 510(k) submission. Send completed forms to Frances Daniel (Frances.Daniel@fda.hhs.gov), who is collecting data to evaluate the pilot Triage program.

Quick Review Criteria	**Yes**	**No**
1. The division has review experience and knowledge of expected device performance		
2. An extensive consult is not required		
3. TPLC checklist does not raise new postmarket issues		
4. Quick Review checklist only raises minor issues		
5. Division Concurrence		
Comments (optional):		

***Note**: If an answer to **1 or 2** is "No", you do not need to complete the rest of the table or checklists. You can delete sections of the document that were not completed and use the traditional review template. Add the completed portion of this document to the record file of this submission.*

*If the answers to **1**…**4** are all "Yes", first obtain management concurrence for a "quick" review and then email the sponsor (see the TriageProgramSummary.doc for email templates). Note a 510(k) Summary is also required for Quick Review, but it can be obtained and/or revised interactively.*

STEP 1: COMPLETE TOTAL PRODUCT LIFECYCLE (TPLC) CHECKLIST

TPLC (Postmarket)	Yes	N/A
1. A TPLC search was conducted and no postmarket issues were identified.		
2. A TPLC search identified minor or expected postmarket issues, but it was determined that these issues should not impact premarket clearance (please note issues in the final decision summary below).		
3. A TPLC search was conducted and no unexpected, major issues were identified.		
Comments *(optional)*:		

STEP 2: COMPLETE QUICK REVIEW CHECKLIST

Complete the general sections (administrative, device description, etc…) and either the radiological or IVD product specific sections depending on the device under review.

QUALITY ASSESSMENT (GENERAL SECTIONS)

Administrative	Yes	No	N/A
4. CDRH Premarket Review Submission Cover Sheet Form FDA 3514			
5. 510(k) Cover Letter			
6. Indications for Use Statement a) Rx/OTC designation b) OIVD Format			
7. Truthful and Accuracy Statement signed by responsible person of the firm (not consultant)			
8. Class III Summary & Certification Form signed by responsible person of the firm (not consultant)			
9. Standards Data Report Form (Form FDA 3654)			
10. Financial Certification/Disclosure Statement			
11. ClinicalTrials.gov certification form (Form FDA 3674), if applicable.			
12. If this is a bundled submission, do these devices/indications qualify for review in a bundled 510(k) per the bundling guidance?			
13. Identification of all related submissions [Pre-IDE, IDE, NSE, deleted, withdrawn 510(k)] with a response to all issues/recommendations outlined in prior communications for related submissions			

Organization, Format, Content	Yes	No	N/A
14. Language a) Content used to support the submission is written in English (including translations of test reports, literature articles, etc.). b) The language in the submission is comprehensible			

Organization, Format, Content	Yes	No	N/A
15. Organization a) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.) b) Submission contains Table of Contents c) The submission has numbered pages			
Comments *(optional)*:			

Device Description	Yes	No	N/A
16. Submission contains appropriate descriptive information recommended in the device specific guidance document. *(N/A if there is no device specific guidance. If the sponsor omitted something without appropriate rationale check "No" and include a comment about what is missing)*			
17. A description of the principle of operation and mechanism of action for achieving the intended therapeutic/diagnostic effect			
18. Description of conditions of use			
19. Description of manufacturing process if needed to determine SE. *This will likely be N/A for most devices.*			
20. A list and description of each model under review in the submission			
21. Submission contains engineering drawing(s)/ schematics/ illustrations/figures of the device as necessary to describe the device design and operation			
22. The device is intended to be marketed with multiple components, accessories, and/or as part of a system (addressing the following items as applicable) a) description provided for each component/ accessory b) 510(k) number provided for each component/accessory that received prior 510(k) clearance c) engineering drawings/schematics/illustrations/figures provided for components/accessories			
Comments *(optional)*:			

Substantial Equivalence Discussion	Yes	No	N/A
23. Has the sponsor identified a predicate(s) a) Predicate(s) 510(k) number, trade name, and model number provided b) The identified predicates are consistent throughout the submission			
24. Detailed comparison of the predicate(s) and the subject device(s), including the following as necessary a) Indications for use (including intended populations) b) Technological characteristics c) Features d) Principle of operation			
25. Analysis of differences between the predicate(s) and subject device with rationale for why/how differences do/don't affect safety or effectiveness			
26. Rationale provided for each element in the Decision Making Flowchart (i.e., the sponsor's rationale for SE determination) (Flowchart) *(has the sponsor provided some discussion regarding how they concluded their device is SE to the cited predicates?)*			

Substantial Equivalence Discussion	Yes	No	N/A
Comments *(optional)*:			

Software and Hazard Analysis	Yes	No	N/A
27. Software "Level of Concern" is consistent with device specific guidance document and/or predicate(s)			
28. Appropriate software documentation provided based on level of concern			
29. Submission includes device (including software) hazard analysis with: a) Description of hazard and hazard severity b) Cause of hazard c) Method of hazard control or mitigation d) Description of testing completed to verify control action adequately mitigates hazard			
Comments *(optional)*:			

QUALITY ASSESSMENT (RADIOLOGICAL)

Proposed Labeling	Yes	No	N/A
30. Prescription Use Statement			
31. Indications for use (identical to IFU form and 510(k) Summary)			
32. Instructions for Use			
33. Relevant hazards, warnings, precautions, contraindications			
34. Contact Information			
35. Labeling includes as recommended in device specific guidance document. *(N/A if there is no device specific guidance. If the sponsor omitted something without appropriate rationale check "No" and include a comment about what is missing)*			
36. Claims made in the labeling are within the scope of the proposed indications and substantiated with data (e.g., literature, test data) as necessary			
Comments *(optional)*:			

Electrical, Sterilization, Biocompatibility, Performance	Yes	No	N/A
37. Evaluation of electrical safety per IEC 60601-1 or equivalent recognized standard			
38. Evaluation of electromagnetic compatibility per IEC 60601-1-2 or equivalent recognized standard			
39. Biocompatibility assessment with appropriate tests			
40. If the device or a device component is used sterile, the submission provides: a) Sterilization method stated for each component (including parameters, e.g., dry time for steam method, EO residuals, radiation dose, etc.) b) Description of method to validate the sterilization cycle c) Description of packaging to maintain device sterility d) SAL level stated e) If product labeled "pyrogen free," a description of the method used to make determination (e.g., LAL)			

Electrical, Sterilization, Biocompatibility, Performance	Yes	No	N/A
41. Shelf-life stated, with supporting validation			
42. Full test report for each completed test			
43. Performance data outlined in device specific guidance document *(N/A if there is no device specific guidance. If the sponsor omitted something without appropriate rationale check "No" and include a comment about what is missing)*			
44. Devices used in any comparative evaluations are identified as predicates in the 510(k) summary and included in Substantial Equivalence discussion			
Comments *(optional)*:			

QUALITY ASSESSMENT (IVD)

Proposed Labeling	Yes	No	N/A
45. Labeling includes the Rx use statement per 809.10 N/A if not indicated for Rx use)			
46. General Labeling Requirements a) Name and place of business of the manufacturer, packer, or distributor, per 809.10 b) Device common or usual name stated c) Quantity of contents *(if applicable)*			
47. The manual (e.g., instructions for use, package insert, etc. is provided and includes: a) Indications for use (identical to IFU form and 510(k) Summary) b) Print date or date of latest revision of manual per 809.10 (required for Rx device and recommended for all other devices) c) Relevant hazards, warnings, precautions, contraindications (generic statements at front of manual, specific within the appropriate sections) d) Adequate instructions for use per 809.10 e) Contact information within US			
48. The provided labeling includes all information recommended in device specific guidance document. *(N/A if there is no device specific guidance. If the sponsor omitted something without appropriate rationale check "No" and include a comment about what is missing)*			
49. Promotional and performance claims made in the labeling are within the scope of the proposed indications and substantiated with data (e.g., literature, test data) as necessary			
50. The provided labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.			
Comments *(optional)*:			

IVDs Performance	Present	Acceptable (Yes)	Acceptable (No)	Not Present	N/A
51. Analytical studies (performance characteristics) and associated protocols, including the line data that are needed. a) Precision / reproducibility at 3 sites if applicable b) Linearity (if applicable) c) Detection limits (LoB, LoD and LoQ if applicable) d) Analytical specificity e) Assay cut-off (if applicable) f) Method comparison (or if applicable, comparison to clinical outcome) g) Matrix comparison (if applicable) h) Reference range (if applicable) i) Disinfection (if applicable) j) Stability protocol and acceptance criteria (if applicable)	a) b) c) d) e) f) g) h) i) j)				
52. Clinical studies: In addition to the analytical studies noted above, performance characteristics for the following clinical studies were included (including protocols and line data): *(List the clinical studies performed in the space below)*					
53. All study protocols, reports, data, and criteria were reviewed and found acceptable. The device was found to demonstrate expected performance, comparable to the predicate device (kxxxxx)					
Optional Reviewer Comments *(Use this space if you need to document any comments about this review section)*:					

Note to Reviewer: Acceptability of data can be determined during Step 4 "Complete Focused Review" below.

510(K) SUMMARY

The 510(k) Summary for IVDs should generally follow the content and format of the OIVD Decision Summaries that are posted online. The 510(k) Summary for radiological devices should follow the Office of Device Evaluation's 510(k) Summary Checklist (also, refer to 21 CFR §807.92). Please note that a detailed 510(k) Summary is needed for clearance of Quick Review submissions. You may need to work interactively with the sponsor to obtain a detailed 510(k) Summary.

Note to Reviewer: In general, submissions with 510(k) Statements do not qualify for Quick Review; however, if only the presence of a 510(k) Statement is preventing Quick Review, please ask the sponsor for a 510(k) Summary. If the sponsor chooses to not provide a 510(k) Summary, please place the submission in the Regular Review Tier and use the traditional review template to complete your premarket review.

STEP 3: EMAIL SPONSOR (*See sample e-mails in Triage Pilot Program Summary document*)

Please inform the sponsor that their submission qualifies for the Quick Review once Division concurrence is obtained.

STEP 4: COMPLETE FOCUSED REVIEW

Please complete a focused review of the submission and work interactively with the sponsor to resolve any minor review issues (if any). Please ensure that the sponsor provides a detailed 510(k) Summary that contains complete performance information, including summary data tables.

Conversion to Regular Review (if necessary)

If significant issues are identified and/or the submission needs to be placed on hold, the submission should be removed from Quick Review and placed in the Regular Review tier. Complete the table below *only* when submissions are removed from the Quick Review.

The submission no longer qualifies for Quick Review due to:	**Yes**
Significant issues in labeling	
Significant issues in performance studies	
Sponsor does not respond in a timely manner (i.e. non-response prevents clearance within 30 day target)	
Extensive consult needed (e.g. statistical consult, clinical consult, or any other significant consult)	
Other (please summarize):	

If the submission no longer qualifies for Quick Review, please delete the remaining sections of this document and use the traditional review template. Add the completed portion of this document to the record file of the submission.

STEP 5: SUBSTANTIAL EQUIVALENCE DETERMINATION

	Yes	**No**	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See 510(k) Flowchart in eRoom to assist with the decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how the new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can or cannot be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

Additional Review Comments (if necessary):

IVD Reviewers please include the following statement to this review memo: All study protocols, reports, data, and criteria were reviewed and found acceptable. The device was found to demonstrate expected performance, comparable to the predicate device (kxxxxx).

Note to IVD Reviewer: Please make sure to check that you have checked the acceptable boxes in the performance checklist table above. Also, please make sure the 510(k) Summary contains sufficient information regarding device performance.

Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

Reviewer Signature: _____ Date: _____

Management Concurrence: _____ Date: _____

Attachments (will be made public)

- Indications for Use Statement
- 510(k) Summary
- Boilerplate Triage-Quick Review Statement

Attachments (for record file):

- 510(k) Cover Sheet / Checklist / Flowchart
- TPLC Search Printout
- Final Draft Labeling (if revised interactively)
- Documentation of Interactive Review (emails, additional information)