Appendix 3C. Review Memorandum Template and Instructions for Instrument Only Submissions

A. 510(k) Number:

Indicate the 510(k) tracking number assigned to the document.

B. Purpose for Submission:

Indicate the reason for submission of this 510(k), i.e., reagent formulation changes, labeling changes, software changes, etc.

C. Manufacturer and Instrument Name:

State the name of the manufacturer and the instrument name.

D. Type of Test or Tests Performed:

State whether the test is either quantitative or qualitative. Indicate the technology, e.g., ELISA, RT-PCR.

E. System Descriptions:

1. Device Description:

   Provide a brief description of the characteristics of the device, that is, design, model, components, etc., (i.e., the make up of the device).

2. Principles of Operation:

   Provide a description of the technology utilized in the device. Discuss the principles of the device methodology, and indicate whether it is well established or new and unproven.

3. Modes of Operation:

   Describe modes of operation, e.g., random access, batch, stat, open tube, closed tube, automatic, mode.

4. Specimen Identification:

   Describe how specimens are identified, e.g., barcode, rack/position, instrument auto numbering.

5. Specimen Sampling and Handling:

Describe how specimens are mixed (for whole blood), sampled (i.e., direct open tube or closed tube piercing), and handled (e.g., manual).

6. Calibration:

   Describe the calibration procedures for the system, i.e., use of whole blood and commercial calibration materials.

7. Quality Control (QC):

   Describe quality control procedures and use of commercial quality control materials. For Point-of-Care or home-use devices, i.e., handheld meters, describe any electronic QC procedures.

8. Software:

   Describe the kind of software the system uses, e.g., operating system, user interface, data management, communications, laboratory information system. Also state whether FDA has reviewed the applicant's Hazard Analysis and Software Documentation previously.

F. Regulatory Information:

1. Regulation section:

   Provide the relevant Code of Federal Regulations sections for the device, e.g., 21 CFR section 864.5220, automated differential cell counter.

2. Classification:

   State whether the device is class I, II, or III.

3 Product code:

   Indicate the specific code for the device.

4. Panel:

   State the regulatory panel for the device: Chemistry (75), Hematology (81), Immunology (82), Microbiology (83), Pathology (88), Toxicology (91).

G. Intended Use:

State the final version of the intended use statement, i.e., as it will appear in the labeling of the device.

1. Indication(s) for Use:

   State the specific indication(s) for which the instrument will be used.

2. Special Conditions for Use Statement(s):

   Describe any special applications of the device (see 809.10) or specific contraindications or indications for use not addressed in the Intended Use Statement, if applicable, e.g., OTC, waived, POC, home-use.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   Provide the name(s) of the legally marketed device(s) with the same intended use to which substantial equivalence is claimed. List the 510(k) submission number(s) for the predicate device(s) for which substantial equivalence is claimed.

2. Comparison with Predicate Device:

   Provide a side-by-side comparison of the technological and analytical characteristics for the new device and the predicate. For example, see table below:

Similarities		
Item	**Device**	**Predicate**

Differences		
Item	**Device**	**Predicate**

I. Special Control/Guidance Document Referenced (if applicable)

List any recognized standards or relevant guidance referenced. Describe modification(s) to recognized standards (if any).

J. Performance Characteristics*:*

The type of data to be provided in this section depends on the intended use, technological characteristics of the new device, and on claims made by the manufacturer.

1. Analytical Performance:

a. *Accuracy*:

Compare each test parameter to either a reference method or a predicate device with the same intended use. Use a testing pool that contains samples representative of the appropriate population. Include an equal number of males and females for which samples span the reportable range. Include specimens that are close to the clinically critical decision point(s). Present the data using linear regression, including 95% confidence intervals for the slope and y-intercept. Provide scatter plots.

b. *Precision/Reproducibility*:

Provide estimates of intra-, inter, lot-to-lot, operator–to-operator, and total imprecision for each measured parameter of the device using samples that span the testing range.

c. *Linearity*:

Provide information on how linearity was established. Indicate whether this conformed to EP6-PS or any other appropriate methodology.

d. *Carryover*:

Provide studies to demonstrate lack of over estimation of results due to carryover effect. The testing pool should consist of samples at clinically meaningful levels.

e. *Interfering Substances*:

Provide studies to show possible interference of substances such as lipids, hemoglobin, bilirubin, etc.

2. Other Supportive Instrument Performance Data Not Covered Above:

Provide other clinical supporting data such as clinical monitoring data, etc.

K. Proposed Labeling

Indicate whether the labeling is sufficient and it satisfies the requirements of 21 CFR section 809.10.

L. Conclusion:

State the rationale for the substantial equivalence (SE) decision.

M. Administrative Information:

1. Applicant Contact Information:

   Report the mailing address and contact information of the applicant, and identify the contact person responsible for the information.

2. Review Documentation:

   Record all applicable information for the administrative record, e.g., the submission chronology, phone memos, faxes, e-mails, meeting minutes, discussions regarding labeling issues.

REVIEW MEMORANDUM

INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

B. Purpose for Submission:

C. Manufacturer and Instrument Name:

D. Type of Test or Tests Performed:

E. System Descriptions:

1. Device Description:
2. Principles of Operation:
3. Modes of Operation:
4. Specimen Identification:
5. Specimen Sampling and Handling:
6. Calibration:
7. Quality Control:
8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes_____ or No_____

F. Regulatory Information:

1. Regulation section:
2. Classification:
3. Product code:
4. Panel:

G. Intended Use:

1. Indication(s) for Use:

2. Special Conditions for Use Statement(s):

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

2. Comparison with Predicate Device:

Similarities		
Item	**Device**	**Predicate**

Differences		
Item	**Device**	**Predicate**

I. Special Control/Guidance Document Referenced (if applicable):

J. Performance Characteristics*:*

1. Analytical Performance:

   a. Accuracy:

   b. Precision/Reproducibility:

   c. Linearity:

   d. Carryover:

   e. Interfering Substances:

2. Other Supportive Instrument Performance Data Not Covered Above:

K. Proposed Labeling

L. Conclusion:

M. Administrative Information:

1. Applicant Contact Information:

a. *Name of applicant:*

b. *Mailing address:*

c. *Phone #:*

d. *Fax #:*

e. *E-mail address (optional*):

f. *Contact:*

2. Review Documentation: