SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K261867

B Applicant

Cepheid

C Proprietary and Established Names

Xpert Carba-R

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
POC, PMY	Class II	21 CFR 866.1640 Antimicrobial susceptibility test powder	Microbiology
OOI	Class II	21 CFR 862.2570 Instrumentation for clinical multiplex test systems	Clinical Chemistry

II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's own CLASS II device requiring 510(k). The following items are present and acceptable.

1. The name and 510(k) number of the **SUBMITTER'S** previously cleared device.

2. Submitter's statement that the **INDICATIONS FOR USE/INTENDED USE** of the modified device as described in its labeling **HAS CHANGED** along with the proposed labeling which includes instructions for use and package insert. The labeling changes are considered minor and do not affect the intended use of the original or modified device.

   The **changes** in the Intended Use/Indications for Use statement of the modified device (K261867) aim to:

a) Replace the term “Assay” with “test” throughout the Intended Use to maintain consistency across all Cepheid products, since “Assay” (or “test”) is not meant to be part of the device name.

b) Update the terminology from "Enterobacteriaceae" to "Enterobacterales" to reflect current taxonomic nomenclature.

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   The **changes** in the labeling of the modified device (K261867) aim to:

   a) Update labeling to reflect the most recent *in silico* inclusivity analysis and wet-testing, including reclassification of select carbapenemase subtypes and addition of newly identified subtypes.

   b) Revise the limitations to reflect outcomes from the updated *in silico* inclusivity analysis and supplemental wet-testing.

4. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.

5. A Design Control Activities Summary which includes:

   a) Identification of Risk Analysis methods used to assess the impact of the modification on the device and its components, and the results of the analysis.

   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modifications and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.