# SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
# DECISION SUMMARY

## I Background Information:

### A 510(k) Number

K243625

### B Applicant

Cepheid

### C Proprietary and Established Names

Xpert MRSA/SA SSTI

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| NQX | Class II | 21 CFR 866.1640<br>Antimicrobial Susceptibility Test Powder | MI – Microbiology |
| OOI | Class II | 21 CFR 862.2570<br>Instrumentation for clinical multiplex test systems | CH – Clinical Chemistry |

## II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's (i.e., Cepheid's) own **CLASS II** device requiring a 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 **INTENDED USE/INDICATIONS FOR USE** of the modified device as described in its labeling **HAS CHANGED** along with the proposed labeling which includes instructions for use and package inserts. These 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 (K243625) aim to:

   (a) Incorporate by name the "GeneXpert Instrument Systems" family of instruments—in order to accommodate a new member (the GeneXpert Infinity Systems) of this family whose other members represent instruments that were previously cleared with the predicate (K080837).

   (b) Modify the device name from the previous "Cepheid Xpert MRSA/SA SSTI Assay" to "Xpert MRSA/SA SSTI" in the Intended Use/Indications for Use statement.

(c) Describe the modified device as a "test" (which incorporates assay and instrument) instead of as an "assay" as was previously done.
(d) Apply minor clarifying changes to the text of the Intended Use/Indications for Use statement.

**The changes** in the labeling of the modified device (K243625) aim to provide the End User/Customer with a set of updated operational documents, i.e., operator manual for the newly added *GeneXpert Infinity System* instruments, updated user instructions for performing the *Xpert MRSA/SA SSTI* test on new and existing instruments, and an updated assay definition file containing assay specifics to be imported to the newly added instruments.

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

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 method(s) 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 modification(s) 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.