SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K200866

B Applicant

Hologic, Inc.

C Proprietary and Established Names

Aptima Combo 2 Assay (Panther System) and Aptima Combo 2 (Tigris System)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QEP	Class II	21 CFR 866.3393 - Nucleic Acid Detection System for Non-Viral Microorganism(s) Causing Sexually Transmitted Infections.	MI - Microbiology
LSL	Class II	21 CFR 866.3390 - Neisseria spp. direct serological test reagents	MI - Microbiology
MKZ	Class I, reserved	21 CFR 866.3120 - Chlamydia serological reagents	MI - Microbiology

II Review Summary:

The 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 NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and Customer Technical Bulletin notifying the users of the change implemented to the Probe reagent.

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. This change was for modification of the Probe reagent by adding a second CT detection probe nucleotide targeting an independent sequence from the current CT detection probe.** The updated version of the Aptima Combo 2 Assay thus includes a dual (redundant) CT detection probe which hybridizes the amplicon in a tandem arrangement with the original probe. This modification not only identifies all recently emerged variants of CT but is also intended to provide diagnostic protection against future genetic variants within the AC2 probe region.

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.