



SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K200436

B Applicant

Hologic, Inc.

C Proprietary and Established Names

Aptima Combo 2 Assay (Panther) - 250 test kit, Aptima Combo 2 Assay (Tigris) - 250 test kit, Aptima Trichomonas Vaginalis (Panther) - 250 test kit, Aptima Trichomonas Vaginalis (Tigris) - 250 test kit

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
MKZ	Class I, reserved	21 CFR 866.3120 - Chlamydia Serological Reagents	MI - Microbiology
LSL	Class II	21 CFR 866.3390 - Neisseria spp. direct serological test reagents	MI - Microbiology
OUY	Class II	21 CFR 866.3860 - Trichomonas vaginalis nucleic acid assay	MI - Microbiology
QEP	Class II	21 CFR 866.3393 - Nucleic acid detection system for non-viral microorganism(s) causing sexually transmitted infections ²²	MI - Microbiology

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 NOT CHANGED** along with the proposed labeling which includes instructions for use and package labeling.
3. A description of the device **MODIFICATION(S)** was provided in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed. This change was for introducing Ready Made Reagents, i.e., in liquid format, as an alternative to the currently marketed lyophilized reagents.**
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.