



SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K243935

B Applicant

Hologic, Inc.

C Proprietary and Established Names

Aptima CMV Quant Assay

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PAB	Class II	21 CFR 866.3180 - Quantitative Cytomegalovirus Nucleic Acid Tests For Transplant Patient Management	MI - Microbiology

II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter'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 approved device.
2. Submitter's statement that the **INTENDED USE/INDICATIONS FOR 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, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATIONS(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 the use of proteinase K enzyme to treat plasma samples with an ML2 flag (clog). Manual pretreatment of plasma specimens with proteinase

K degrades proteins, preventing coagulation of specimens when exposed to alkaline shock, resulting in valid assay results. Since the prevalence of plasma specimens that cause ML2 flags in the Aptima Assay at customer sites was calculated to be 0.54%, it is expected that the use of the proteinase K protocol will be very limited since it will be used only with samples that already had an ML2 flag invalid result.

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 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 special 510(k) paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or approved) device.