SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K233688

B Applicant

Quidel Corporation

C Proprietary and Established Names

Sofia 2 SARS Antigen+ FIA; Sofia 2 SARS Antigen+ FIA Control Swab Set

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QVF	Class II	21 CFR 866.3982 - Simple Point-Of-Care Device To Directly Detect SARS-Cov-2 Viral Targets From Clinical Specimens In Near-Patient Settings	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. A description of the device labeling modifications, including sufficient detail to demonstrate that the fundamental scientific technology of the modified device has not changed. **These changes were to revise the intended use to: 1) clarify that serial testing with an antigen test may be omitted if primary testing is instead followed up with molecular testing; and 2) clarify statements regarding result interpretation to align with the Special Controls described in 21 CFR 866.3982.**

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

4. A Summary of Design Control Activities was not provided nor requested, as the labeling modifications proposed therein identified no new risk or significantly modified existing risk and did not indicate that the modifications had the potential to affect product performance.

The labeling for this modified subject device has been reviewed to verify that the instructions for use have been modified to reflect the updated intended use. 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. On this basis, I recommend the device be determined substantially equivalent to the previously cleared device.