January 11, 2024

Foundation Medicine, Inc.
Louisa Walker
Associate Director, Regulatory Affairs
150 Second Street
Cambridge, Massachusetts 02141

Re: P170019/S048
Trade/Device Name: FoundationOne CDx (F1CDx)

Dear Louisa Walker:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its review of your premarket approval application (PMA) Supplement and issued an Approval Order on November 16, 2023. We inadvertently made an error in ommitting the company name (Foundation Medicine, Inc.) in the address block.

We hope that this omission has not inconvenienced you. If you have any questions about this corrective action, please contact Timothy Schaefer at 301-796-6886 or Timothy.Schaefer@fda.hhs.gov.

Sincerely,

Donna M. Roscoe -S

Donna Roscoe, Ph.D.
Acting Director
Division of Molecular Genetics
and Pathology
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health