August 5, 2024

Elizabeth Mansfield, Ph.D.
Vice President, Regulatory Policy
Foundation Medicine
400 Summer Street
Boston, MA 02210

Sent via email to: emansfield@foundationmedicine.com

Re: Reclassification Petition – Docket Number FDA-2024-P-3484

Dear Petitioner:

Your submission requesting that FDA reclassify all next-generation sequencing oncology panel devices used for somatic or germline variant detection that include one or more companion diagnostic indications (categorized under product code PQP) from class III to class II was received and processed under 21 CFR 10.30 by this Office on July 25, 2024.

It was assigned docket number FDA-2024-P-3484. Please refer to this docket number in future correspondence on this matter with the Agency.

Please note, the acceptance of this petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Rachel Park -S (Affiliate)
Digitally signed by Rachel Park -S (Affiliate)
Date: 2024.08.05 08:25:53 -04'00'

Rachel Park
Regulatory Counsel
Office of Policy
Center for Devices and Radiological Health