February 11, 2026

Rakshith Katta Director of Regulatory Affairs
SMO India Clinical Research Pvt. Ltd.
#261, 15th Main, Sadashiva Nagar, RMV Extension
Bengaluru, Karnataka, India 560080

RECOGNITION LETTER

Dear Rakshith Katta:

The Center for Devices and Radiological Health (CDRH) has completed the review of your application as a Third Party Review Organization of selected premarket notifications [510(k)s]. Based on the information we received, CDRH has decided to recognize (i.e., accredit) your organization. This recognition will be reflected on the Food and Drug Administration (FDA) website at the time of the next scheduled update (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfthirdparty/accredit.cfm)

This recognition allows your organization to review eligible device types (Product Codes) that fall under the regulations listed in an attachment to this letter. The device types in this list will also be identified on the FDA website as eligible for review by your organization. As stated in your application, you will limit work to that for which competence and capacity are available. This will include ensuring that designated personnel are qualified in all of the scientific disciplines necessary for review of the 510(k)s accepted for review by SMO India Clinical Research Pvt. Ltd.. Per section 523(b)(2)(D)(i) of the Food, Drug and Cosmetic (FD&C) Act , your recognition will remain valid until February 11, 2029, unless subject to suspension or withdrawal as outlined in section 523(b)(2)(B) of the FD&C Act. It will be your responsibility to apply for rerecognition to maintain participation in the 510(k) Third Party Review Program.

You are expected to maintain compliance with your signed certification statements, and criteria for participation in the 510(k) Third Party Review Program with regard to independence, personnel qualifications, capacity, infrastructure, facilities, good documentation practice and freedom from conflicts of interest. Failure to do so may result in suspension or withdrawal of recognition, after you are provided notice and an opportunity for an informal hearing, from the list of accredited third party reviewers[1]. It will be your responsibility to apply for rerecognition to maintain participation in the 510(k) Third Party Review Program.

[1] See section 523(b)(2)(B) of the FD&C Act.

FDA performs assessments of 510(k) Third Party Review Organizations on a periodic or "for cause"basis as part of its auditing to ensure 510(k) Third Party Review Organizations continue to meet the standards of recognition. [2] In addition, FDA evaluates completed premarket reviews of 510(k)s submitted to FDA under the 510(k) Third Party Review Program and provides feedback to 510(k) Third Party Review Organizations following its audits. 510(k) Third Party Review Organizations should continue to demonstrate technical competency to maintain recognition.

Please direct any questions that you may have to the 510(k) Third Party Review Program inbox at 3P510k@fda.hhs.gov

Sincerely Yours,

JOSHUA C. NIPPER -S
Digitally signed by JOSHUA C. NIPPER -S
Date: 2026.02.11 16:37:01 -05'00'

Joshua C. Nipper, M.E.
Director
Division of Regulatory Programs 1
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Attachment - List of Eligible Device Types for Review by SMO India Clinical Research Pvt. Ltd.

LIST REGULATIONS BY PANEL (a complete list of Product Codes is listed in Decision Memo).

Medical Speciality	Count of Product Codes
Anesthesiology	69
Cardiovascular	108
Radiology	57
Neurology	66
Dental	72
Toxicology	200
Clinical Chemistry	157
Ophthalmic	62
Obstetrics/Gynecology	93
Orthopedic	2
Hematology	105

[2] See section 523(b)(2)(C) of the FD&C Act.

Physical Medicine	32
General Hospital	67
General & Plastic Surgery	59
Immunology	124
Ear Nose & Throat	17
Gastroenterology	76
Pathology	2
Microbiology	99
Molecular Genetics	1

Grand Total: 1468 Product Codes.