



Acknowledgement Letter

04/01/2025

Kenneth Kleinhenz, Official Correspondent
QSR Consulting
10807 Dakota Ranch Rd.
Santee, CA 92071
UNITED STATES

Dear Kenneth Kleinhenz:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned. Failure to do so may result in processing delays. Please send any future correspondence through the CDRH Portal. For more information on the CDRH Portal, please visit [CDRH Portal](#). If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: K231622/A001
Received: 04/01/2025
Applicant: REGER Medizintechnik, GmbH
Device: REGER Nebulizer Irrigation Cannula

We will notify you when the review of this document has been completed or if any additional information is required. As a reminder, submissions should include the minimum (i.e., least burdensome) amount of information necessary to adequately address its specific regulatory purpose. In accordance with FDA's "[The Least Burdensome Provisions: Concept and Principles](#)", FDA will assess submitted information for relevance to the submission's purpose, but if information is deemed not relevant, it will not be reviewed further and will not be part of the decision-making process. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please visit [Device Advice: Comprehensive Regulatory Assistance](#).

Sincerely yours,

Center for Devices and Radiological Health