June 24, 2020

Mr. Suleman Farrukh
Chief Executive
Micromech Instruments Corporation
787 Marala Road, Nai Abadi Murad Pur
P.O. Box 816
Sialkot, 51310, Pakistan

&

Mr. Mohammad Ashraf
Lead Auditor
Quality Management Consultants
Bait-Ul-Asraf, Khadim Ali Road
Sialkot, 51310, Pakistan

Subject: CMS Case 608126 – FEI Number – 3003820624 - Request to be added to the green list of Import Alert #76-01

Dear Mr. Farrukh and Mr. Ashraf:

On November 11, 2019, your firm Micromech Instruments Corporation was audited by Quality Management Consutants. The auditor found two non-compliances. Subsequently, your firm submitted a corrective action plan and was re-inspected on November 25, 2019. The auditor certified that your firm complied with the Quality System regulation and requested that your firm be added to the green list on November 27, 2019. After receiving this letter, Center for Devices and Radiological Health (CDRH) reviewed the information and determined that your firm could not be added to the green list of Import Alert #76-01 because your firm did not provide a Hardness test report for the correct batch and lot number, it did not appear the firm was destroying samples used for Hardness and Copper Sulfate testing and your firm did not appear to have correctly accounted for the number of rejected samples.

On April 15, 2020, Mr, Farrukh responded to the FDA Non-Concur letter issued to your firm on February 18, 2020. In the cover letter, Mr. Farrukh addressed each of the issues noted in the previous FDA Non-Concur letter. He provided a Hardness Test report with the correct lot and batch number for the Kelly Rankin Hemostatic Forceps CVD. The Hardness test results were within the acceptable range. Mr. Farrukh also explained that the samples used for Hardness and Copper Sulfate had previously been retained for 5 years for future reference and re-testing. However, upon receiving the FDA Non-Concur letter, the firm updated their SOP #7 (Inspection and Test) to specify that the test samples needed to be destroyed. Your firm also provided a copy of the revised SOP as well as records showing the test samples were destroyed. Lastly, your firm

provided an explanation for all rejected devices, these includes: the starting quantity of devices in the lot, the number of pieces rejected at each stage and the final quantity of packed devices.

FDA has reviewed the firm's April 20th letter, the corrected Hardness Report and other documentation provided in this case. It has been determined that the documentation provided appears adequate, in that, the quality systems implemented at the manufacturing establishment is adequate: and marketing of these medical devices in the U.S is acceptable. Therefore, your firm **w**ill be added to the green list of Import Alert 76-01, "Exempt from Detention Without Physical Examination of Medical Instruments from Pakistan".

Micromech Instruments Corporation must pay the Fiscal Year 2020 annual registration user fee, register their establishment and list their devices prior to importing or offering any medical devices for import into the United States. Instructions for how to pay the annual registration user fee, register your establishment and list the devices can be found on our website at https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing in the "Tutorial" section. If you need assistance with paying the annual registration user fee, please send an email to the User Fee Helpdesk at userfees@fda.gov. If you need assistance with registration or listing, please send an email to the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.

If you have any questions regarding this correspondence, or need further assistance, please contact Lisa Marie King at lisam.king@fda.hhs.gov or (301)796-5785.

Sincerely yours,

FDA

Digitally signed by Tanisha L. Hithe -S
Date: 2020.06.24 20:28:05 -04'00'

Lisa Marie King
Consumer Safety Officer
Imports and Registration & Listing Team
Division 2: Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health