DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 66
Silver Spring, MD 20993

Via United States Postal Service

Jacques Ouellet
General Director and Chief Executive Officer
NSE Automatech
520 Rutherford Street
Granby, Quebec J2G 0B2
Canada

JAN 1 3 2017

FEI: 3009293341

Dear Mr. Ouellet:

The United States Food and Drug Administration (FDA) conducted a facility inspection of the premises at Granby, Quebec, Canada, on November 28, 2016, through December 1, 2016.

At the conclusion of the inspection, the Form FDA 483, List of Inspectional Observations, was not issued. However, there were objectionable conditions found during the inspection that do not appear to warrant consideration of regulatory follow-up at this time. These problems were reported to you and formally discussed with your firm's management during the inspection. All of the corrections and corrective actions will be verified during the next routinely scheduled inspection. Note that corrections and corrective actions must address systemic problems.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The FDA expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

While your establishment has objectionable conditions that should be corrected, a written response to this letter is not necessary.

If you are not aware, it may be of interest to you to know that FDA is currently participating in a Medical Device Single Audit Program (MDSAP) Pilot alongside other international partners. For more information about the MDSAP Pilot, please refer to the following internet link at the FDA website:
http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/default.htm.

If you have any questions about the contents of this letter, please contact Daniel Walter, Chief, Foreign Enforcement Branch, at feb@fda.hhs.gov (email) or +1(240)402-4020 (telephone).

Sincerely yours,

for Matthew Krueger, M.S.E.
Acting Director
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health