



Eddie Moradian, Ph.D.
Chief Executive Officer
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Document Number: GEN1600115

Dear Dr. Moradian:

It has come to our attention that you are currently marketing the Zika Virus RNA by RT-PCR Assay, which is intended "to provide a reliable, accurate and rapid method of testing for Zika virus". The Zika Virus RNA by RT-PCR Assay appears to meet the definition of a device as that term is defined in section 201(h) of the Federal, Food, Drug, and Cosmetic Act.

Based on our review of your website and other materials, we believe you are offering a high risk test that has not been the subject of premarket clearance, approval, or Emergency Use Authorization review by the Food and Drug Administration (FDA). In light of the current public health emergency, it is particularly important for the FDA to review information related to your Zika Virus RNA by RT-PCR Assay's design, validation, and performance characteristics.

We have assigned a unique document number that is cited above. The requested information should reference this document number and should be submitted to:

James L. Woods, WO66-4684
Deputy Director
Patient Safety and Product Quality
Office of *In Vitro* Diagnostics and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dr. Eddie Moradian
MD Biosciences, Inc.

We look forward to discussing this with you, and are committed to working with you as we strive to protect the public health. Please contact us within seven (7) days to schedule a meeting. If you have questions relating to this matter, please feel free to call Patricia Spillar at 301-796-6191.

Sincerely yours,

James L. Woods -A
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James L. Woods
Deputy Director Patient Safety
And Product Quality
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and
Radiological Health