DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Rajasingam S Jeyendran
DNA-Cardiocheck, Inc.
2292 Regency Woods Drive
Lisle, IL 60523

NOV 0 2 2015

Document Number: GEN1500296

Dear Mr. Rajasingam Jeyendran:

It has come to our attention that you are currently marketing a direct-to-consumer test, the DNA-CardioCheck, which is intended to test for DNA genetic markers linked to thrombophia, deep-vein thrombosis, cardiovascular disease and stroke. The DNA-CardioCheck 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.

We have conducted a review of our files, and have been unable to identify any FDA clearance number for the DNA-CardioCheck. We request that you provide us with the FDA clearance number for this device. If you do not believe that you are required to obtain FDA clearance for the device, please provide us with the basis for that determination.

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, WO66-5688
Deputy Director
Patient Safety and Product Quality
Office of *In Vitro* Diagnostics and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Rajasingam Jeyendran
DNA-CardioCheck

If you have questions relating to this matter, please feel free to call James Nadeau at 240-402-6638, or log onto our web site at www.fda.gov for general information relating to FDA device requirements.

Sincerely yours,

James L. Woods, WO66-5688
Deputy Director Patient Safety and
Product Quality
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and
Radiological Health