



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

February 7, 2019

(b) (6)

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner initiate an investigation by FDA of whether the Applicant for patent extension (referenced in dockets FDA-2017-E-3592 and FDA-2017-E-3616) for the Absorb GTI Bioresorbable Vascular Scaffold (BVS) System acted with due diligence during the regulatory review period was received by this office on 2/6/2019.

It was assigned docket number FDA-2019-P-0622. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby  
Supervisory Administrative Proceedings Specialist  
Division of Dockets Management  
FDA/Office of the Executive Secretariat (OES)