U.S. FOOD & DRUG ADMINISTRATION

Pleximmune™

HDE: H130004

Office of In Vitro Diagnostic Devices and Radiological Health

Center for Devices and Radiological Health

Pediatric Advisory Committee

September 12, 2017

- The approved ADN for Pleximmune™ is 4000 tests total per year.
- During the reporting period between June 01, 2016 to May 31, 2017, 315 Pleximmune™ tests for the total of 231 patients had been performed.
- FDA's Review Team has identified no new safety concerns since September 2016's PAC meeting.
- FDA concludes that the probable benefit/risk profile of the device for the pediatric population continues to support the HDE for which the exemption was granted.
- FDA recommends continued surveillance and will report the following to the PAC in 2018:
  - Annual Distribution Number
  - MDR Review
  - Literature Review

Question to the PAC

Does the Committee agree with FDA's conclusions and recommendations?


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