DEPARTMENT OF HEALTH & HUMAN SERVICES

MAR 1 8 2014

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

Laura Storms-Tyler
Vice President
Olympus Medical Systems Corporation
3500 Corporate Parkway
PO Box 610
Center Valley, Pennsylvania 18034-0610

Document Number: CPT1400142

Dear Ms. Storms-Tyler:

It has come to our attention that you are currently marketing the TJF-Q180V duodenoscope, which is intended for endoscopic diagnosis, treatment and video observation. The TJF-Q180V duodenoscope 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 determined that on May 20, 2008, your firm received 510(k) clearance under K080403 for the XTJFQ160. In the XTJF-Q160, the elevator wire was cleaned and subjected to high level disinfection or sterilization. A review of a video on your firm's website (www.olympusamerica.com ), a brochure (http://www.olympusamerica.com/msg_section/files/TJF-Q180V_DetailAid%5B1%5D.pdf ), and your firm's reprocessing competency (http://www.olympusamerica.com/msg_section/files/ONTRACKReprocessingInService_JF_TJF.pdf) reveals that your firm is marketing a XTJFQ180V duodenoscope with a sealed elevator wire channel. We note that your firm reported that this change was a minor change to the XTJFQ160 and the elevator wire in the XTJFQ180 does not require reprocessing and concluded that a new 510(k) was not required.

However, we believe that sealing the elevator channel, and consequently, preventing sterilization and high level disinfection of the elevator channel, impacts the safe use of the device and would require a new 510(k) submission to allow FDA to evaluate the elevator channel sealing mechanism. If you do not believe that you are required to obtain FDA clearance for the TJF-Q180V duodenoscope, please provide us with the basis for that determination. Please provide the requested information above in thirty business days.

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

Complaints Program Manager, WO66-2621
Division of Risk Management Operations
Office of Compliance
Center for Devices and
Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

If you have questions relating to this matter, please feel free to call Jeene Bailey at 301-796-5770, or log onto our web site at www.fda.gov for general information relating to FDA device requirements.

Sincerely yours,

LaShanda M. Long , Chief
Surveillance and Enforcement Branch I
Division of Premarket and Labeling
Compliance
Office of Compliance
Center for Devices and
Radiological Health