DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

August 9, 2013

FILE COPY

Garrett Skelly, ESQ
160 Centennial Way, Ste. 21
Tustin, CA 92780

Dear Mr. Skelly:

Your petition to the Food and Drug Administration on behalf of Reginald Burgess requesting FDA to amend external prosthetic order and procedures and classification of all external prosthetic devices in 21 CFR 890.3420 and 21 CFR 890.3500 to read as both "Prescription" and "Over The Counter Use" in particular first and foremost for the C-Leg - K991590.Pdf, was received by this office on 8/09/2013. It was assigned docket number FDA-2013-P-0949/CP1, and it was filed on 8/09/2013. 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,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)