DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

March 27, 2020

Pattanam Srinivasan, M.D.
President & CEO
C Laser Inc.
110 N Muirfield Circle
Lebanon, IN 46052

Sent via email to: srinidoc@hotmail.com

Dear Petitioner:

Your petition for reconsideration to the Commissioner of Food and Drug Administration requesting the FDA 1) Overrule the denial order and remove Srilas 7 from automatic Class III to be placed in Class II (or I); 2) Recognize Srilas 7 as a "non significant risk" device for the purpose of a clinical study; 3) Recognize Srilas 7 as a breakthrough device in patient's best interest, consistent with FDA's own written communication dated October 28, 2010 granting the device expedited review status was received by this office on 03/20/2020.

It was assigned docket number FDA-2020-P-1220. 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
Digitally signed by Dynna Bigby
Date: 2020.03.30 15:26:58 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of Operations (OO)