July 17, 2020

Via Email

C Laser Inc.
Dr. Pattanam Srinivasan
President & CEO
110 N. Muirfield Circle
Lebanon, Indiana 46052

Re: Petition for Reconsideration; Docket Nos. FDA-2019-P-2124 and FDA-2020-P-1220

Dear Dr. Srinivasan,

This letter responds to your "Petition[s] for Administrative Reconsideration under §10.33" (hereinafter Petition), filed on April 28, 2019 and March 27, 2020, respectively.[1] Pursuant to authority delegated by the Commissioner of Food and Drugs (the Commissioner) and for the reasons set forth below, I deny your petition.

On September 19, 2017, the Center for Devices and Radiological Health (CDRH) received your De Novo request pertaining to the classification of Srilas 7, Low Intensity Laser Ablation (LILA) System (Srilas 7).[2] On April 3, 2019, CDRH denied C Laser's De Novo request for classification and found that, based on Srilas 7's indications, the Srilas 7 did not meet the criteria under section 513(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for classification into class I or II and that, therefore, the device would remain in class III.[3] CDRH stated that C Laser had not "provided sufficient information to demonstrate that the probable benefits of the device outweigh its probable risks to health" and that C Laser "had not provided sufficient information to enable FDA to develop special controls to mitigate probable risks to health and provide reasonable assurance of safety and effectiveness."[4]

C Laser subsequently filed the instant Petition. Under 21 CFR 10.33, the Commissioner will grant a petition for administrative reconsideration when the Commissioner determines that

[1] Although the latter petition was untimely, the two Petitions for Administrative Reconsideration are, in all meaningful respects, identical. For administrative convenience, therefore, FDA will treat them as a timely-filed single petition, and this letter will serve to respond to that Petition and close both dockets. All references herein refer to the documents contained in FDA-2019-P-2124.
[2] *See* Petition Attachment, De Novo Denial, at 1.
[3] *Id.*
[4] *Id.*

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all the following apply:

1. The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.
2. The petitioner's position is not frivolous and is being pursued in good faith.
3. The petitioner has demonstrated sound public policy grounds supporting reconsideration.
4. Reconsideration is not outweighed by public health or other public interests.[5]

If a petition does not meet the all those criteria, FDA may grant a petition for reconsideration if the agency determines it is in the public interest and in the interest of justice.[6]

By its own terms, your Petition requests reconsideration of the agency's decision to deny your De Novo request.[7] In your Petition, however, you nonetheless include two requests for additional relief. You request that the agency recognize that your device is both "a 'nonsignificant risk' (NSR) device for the purpose of a clinical study" and "a breakthrough device in the patient's best interest, consistent with FDA's own written communication dated October 28, 2010 granting the device expedited review status."[8] These requests for relief do not relate to the decision at issue in your Petition but instead relate to separate decisions, at least one of which occurred more than thirty days before you filed the Petition.[9] I therefore consider these two requests for relief, and their attendant arguments in support, to be irrelevant to the decision at issue in your Petition.

Your Petition has not demonstrated that, in denying your De Novo request, the agency did not adequately consider the relevant information or views contained in the administrative record. Your Petition identifies aspects of the decision letter denying your De Novo request for Srilas 7 with which you disagree, but it does not point to specific instances in which the agency failed to consider all the relevant information and views before denying your De Novo request. Indeed, the decision explains in detail the deficiencies and concerns that would need to be addressed before a De Novo request for Srilas 7 could be granted and even references previous agency communications setting forth similar deficiencies and concerns in relation to your earlier submissions to the agency in connection with this device.[10]

Given that the Petition fails to meet the first of four requirements for granting reconsideration under 21 CFR 10.33, there is no need to address the three remaining requirements. Further, nothing in your petition demonstrates that it would be in the public interest or in the interest of

[5] 21 CFR 10.33(d).
[6] *Id*.
[7] Petition at 1.
[8] *Id.*.
[9] *See* 21 CFR 10.33(b) (requiring that petitions for administrative reconsideration be filed no later than 30 days after the decision involved, absent good cause).
[10] *See* De Novo Denial at 2-6.

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justice to grant the petition; therefore, I find that there is no basis for granting your petition on a discretionary basis and deny your petition.

Sincerely,

Denise M. Hinton -S3

Digitally signed by Denise M. Hinton -S3
Date: 2020.07.17 19:56:20 -04'00'

RADM Denise Hinton
Chief Scientist

cc: Randall G. Brockman, MD, Clinical Deputy Director, Office of Device Evaluation, CDRH
Abiy Desta, CDRH Ombudsman
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