**Review of Laser Submissions #G88-1 (blue book memo) (Text Only)**

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**General Program Memorandum G88-1**

April 22, 1988

Review of Laser Submissions

Purpose

At the present time, submissions for lasers are reviewed by many ODE

divisions; sometimes they receive concurrent review in two or more

divisions. This fragmented review and responsibility compounds the

management of the review process and consistency of labeling, and

increases the time of review for these products. It also creates

confusion and interferes with communications with product sponsors.

The purpose of this guidance memorandum is to consolidate and

streamline the review of submissions for medical lasers and laser

accessories and to establish uniformity of labeling while at the same

time maintaining the high level of expert review we have applied in

the past.

Laser Submission Review

1. At present, DSRD will assume responsibility for laser and laser

accessory 510(k)'d devices of DSRD, DANRD, DGGD, DOED, and DOD.

Each division will inform DSRD of the name of its laser device

contact person who will serve as the liaison with DSRD.

2. New 510(k)s will be the review responsibility of DSRD. Each

division will provide to DSRD a list of intended uses (i.e.,

indication statements) for each type of laser and laser accessory

that has been found equivalent via 510(k), as well as for those

with approved PMA's to assist in making 510(k) decisions.

Respective divisions will be consulted in the review, as DSRD

deems appropriate. With respect to "not substantially equivalent"

decisions, DSRD will obtain review and concurrence of the

respective division involved (reflected in the sign-out of the

submission's yellow sheet).

3. Each division will provide a list of current IDE's that are to

obtain clinical data intended to be submitted in support of

510(k)'s. These ongoing IDEs will be transferred to DSRD. Future

submissions concerning these IDE's,(e.g., supplement), will be

reviewed by DSRD with consultation with the original divisions, as

deemed appropriate by DSRD.

4. All new IDE's will be sent in parallel from DMC to DSRD and the

other division(s) involved. Within 2 working days of division

receipt, DSRD and the division(s) will meet to decide whether the

laser device is likely to proceed to the market via the 510(k)

track or PMA track.

5. All laser devices requiring a PMA, and their respective IDE's will

continue to be reviewed by the divisions responsible for the

medical specialty. DSRD will provide the technical review of

these submissions for the responsible division.

6. A copy of SE, NSE and IDE letters will be forwarded to the

consulting division by DSRD at the time they are issued.

Effective Date: This guidance memorandum is effective immediately.

**[More in Guidance Documents (Medical Devices and Radiation-Emitting Products)](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)**

[Cross-Center Final Guidance](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)[Office of Compliance Final Guidance](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)[Office of the Center Director Final Guidance](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)[Office of Communication and Education Final Guidance](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)[Office of Device Evaluation Final Guidance 2010 - 2016](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)[Office of Device Evaluation Final Guidance 1998 - 2009](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)[Office of Device Evaluation Final Guidance 1976 - 1997](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)[Office of In Vitro Diagnostics and Radiological Health Final Guidance](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)[Office of Surveillance and Biometrics Final Guidance](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)[Office of Science and Engineering Laboratories Final Guidance](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)[Draft Guidance](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)[Radiation-Emitting Products Guidance](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)[Withdrawn Guidance](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)

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