Kit Certification for 510(k)s (Text Only)

For review purposes of a premarket notification (510(k)) for a kit, please provide the certification stated below:

> I certify that the following components of my kit are either (1) legally marketed pre-Amendments devices, (2) exempt from premarket notification (consistent with the exemption criteria described in the classification regulation(s) and the limitation of exemptions for Section 510(k) of the act (e.g., 862.9), or (3) have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is to be intended (i.e., I am not claiming or causing a new use for the component(s)).
>
> I further certify that these components are not purchased in "bulk", but are purchased in finished form, i.e., they are packaged, labeled, etc., consistent with their pre-Amendments, exemption, or premarket notification criteria and status.

If you cannot make the above referenced certification statements for each component of your kit, you must itemize the components without a pre-Amendments exemption, or premarket notification status. In this case we will continue our premarket notification review of these components of your kit.

If you cannot make the above referenced statement in the second paragraph for each component of your kit, you must itemize these components, state whether they are pre-Amendments, exempt, or have been found substantially equivalent through the premarket notification process, and describe how you further process them (e.g., sterilize, package/repackage, label/relabel, etc.).

More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)