Suggested Content for Original IDE Application Cover Letter (Text Only)

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

Suggested Content for Original IDE Application Cover Letter

It is recommended that the cover letter include the following information *in the order provided* to assist in the administrative processing of the application.

1. Statement that the information provided is an original IDE submission.
2. Device Information:

   Device Name
   Intended Use
3. Sponsor contact information:

   Name
   Address
   Contact Person
   Telephone Number
   Fax Number

   Please note that the sponsor MUST be located in United States [21 CFR 812.18(a)].
4. Manufacturer Information:

   Name
   Address
   Contact Person
   Telephone Number
   Fax Number
5. Applicant Information:
   If the organization submitting the application is not the sponsor, such as a consultant or a

lawyer, include contact information for the applicant organization or individual.

6. Provide the following information, if applicable:

   Pre-IDE/Pre-IDE meetings:
   Describe any discussions with the FDA reviewing division regarding this device. If a Pre-IDE was submitted, state the Pre-IDE number and the name of FDA reviewer, if known. If a Pre-IDE meeting occurred, provide the name of the FDA contact person and a copy of the meeting minutes.

   Waiver Requests:
   Identify any requests for waivers and include a justification for the waiver.

   Referenced Files:
   Identify any files that are referenced in the IDE application, such as Premarket Approval, Premarket Notification 510(k), IDE, or device master files. If files were not submitted by the sponsor, include a letter from the owner of the files that grants FDA permission to reference the files in its review of the current application.

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)