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- Procalcitonin (PCT) devices have been evaluated against a clinical comparator (e.g., sepsis definition) as indicated in the special controls associated with CFR 866.3210.[a]
- Consistent with the 510(k) paradigm, for future regulatory applications the performance of PCT devices will be established using a method comparison comparator model where the Indication for Use(s) safety and effectiveness of PCT for that use(s) has been established.
  - This is based on experience from cleared PCT devices, approval of *de novo* DEN150009[b] (CFR 866. 3215), and feedback from the November 10, 2016 meeting of the Microbiology Devices Panel[c].

[a] *Class II Special Controls Guidance Document: Endotoxin Assay*, Issued October 3, 2003. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM070936.pdf

[b] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN150009

[c] http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MicrobiologyDevicesPanel/ucm515517.htm

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- This approach requires demonstration that the analytical performance of a new device is similar to the predicate across the claimed analytical measuring range and at relevant medical decision points.
  - When appropriate, if analytical agreement between the candidate device and the predicate is acceptable, all cleared Indications for Use for PCT could be included in labeling for the new device.
- New Indications for Use would require performance to be established through prospective clinical studies or acceptable alternative mechanisms.
- Sponsors are encouraged to use the Pre-Submission program to obtain FDA feedback prior to a premarket device submission[a].

[a] http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf