FDA Finalizes De Novo Evaluation Guidance and Issues Associated Refuse to Accept Checklist

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On October 30, 2017, the Food and Drug Administration (FDA or the Agency) released its final De Novo request guidance document entitled, De Novo Classification Process (Evaluation of Automatic Class III Designation) (Final Guidance).

This guidance finalizes the draft guidance with the same title that was published on August 14, 2014, and supersedes the related legacy guidance from 1998. The Final Guidance is part of FDA's commitments under the Medical Device User Fee Act (MDUFA IV), where, for the first time, performance goals and submission fees are applied to De Novo requests. Similar to other MDUFA-tracked marketing submissions, De Novo requests will transition to also contain a refuse to accept checklist, the draft guidance for which was published concurrently with the Final Guidance.

Read More: FDA Finalizes De Novo Evaluation Guidance and Issues Associated Refuse to Accept Checklist

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