Evaluation of Automatic Class III Designation (De Novo) Summaries (K123250 letter added)

U.S. Food & Drug Administration

The Food and Drug Administration Modernization Act of 1997 (FDAMA) added the *de novo* classification option as an alternate pathway to classify novel devices of low to moderate risk that had automatically been placed in Class III after receiving a “not substantially equivalent” (NSE) determination in response to a premarket notification [510(k)] submission. Section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA), on July 9, 2012, to allow a sponsor to submit a *de novo* classification request to the FDA for novel low to moderate risk devices without first being required to submit a 510(k).

There are two options for *de novo* classification for novel devices of low to moderate risk.

- Option 1: Any person who receives an NSE determination in response to a 510(k) submission may, within 30 days of receipt of the NSE determination, submit a *de novo* request for the FDA to make a risk-based evaluation for classification of the device into Class I or II.
- Option 2: Any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may submit a *de novo* request for the FDA to make a risk-based classification of the device into Class I or II, without first submitting a 510(k) and receiving an NSE determination.

Devices that are classified through the *de novo* process may be marketed and used as predicates for future 510(k) submissions.

Since 2010, the FDA has begun releasing summary documents for devices classified through the *de novo* process. The *de novo* summary is intended to present an objective and balanced summary of the scientific evidence that served as the basis for the decision to grant a *de novo* request. The *de novo* summary also serves as a resource regarding the types of information necessary to support substantial equivalence for device manufacturers that may wish to use the device as a predicate for future 510(k) submissions.

Links to all available *de novo* summary documents can be found in the table below.

Device Name	510(k) Number	Approval Letter	Decision Summary
Infrascanner Model 1000	K080377	Approval Letter [1]	Decision Summary [2]
Zeltiq™ Dermal	K080521	Approval Letter [3]	

Cooling Device			
Bio-Seal Lung Biopsy Tract Plug System	K082438	Approval Letter [4]	Decision Summary [5]
Erchonia ML Scanner	K082609	Approval Letter [6]	
NuMED NuCLEUS and NuCLEUS-X BAV Catheters	K082776	Approval Letter [7]	Decision Summary [8]
Hem-Avert Perianal Stabilizer	K083692	Approval Letter [9]	
ViruLite Cold Sore Machine	K083767	Approval Letter [10]	Decision Summary [11]
RIDASCREEN Norovirus 3rd Generation EIA	K093295	Approval Letter [12]	
Prostate Mechanical Imager	K093579	Approval Letter [13]	Decision Summary [14]
LipiFlow Thermal Pulsation System	K093937	Approval Letter [15]	Decision Summary [16]
Steris Verify Spore Test Strip for S40	K100049	Approval Letter [17]	Decision Summary [18]
InBios DENV Detect IgM Capture ELISA	K100534	Approval Letter [19]	Decision Summary [20]
Cabochon System	K101231	Approval Letter [21]	Decision Summary [22]
Widex C4-PA Wireless Air-Conduction Hearing Aid	K101699	Approval Letter [23]	Decision Summary [24]
Aptus Endovascular Suturing System	K102333	Approval Letter [25]	Decision Summary [26]
ImmunoCAP Tryptase	K103039	Approval Letter [27]	Decision Summary [28]
Percutaneous Surgical Set with 5 mm or 10 mm Attachments	K110431	Approval Letter [29]	Decision Summary [30]
STRATIFY JCV Antibody ELISA	K112394	Approval Letter [31]	Decision Summary [32]
Neuropsychiatric EEG-Based Assessment Aid for ADHD (NEBA)	K112711	Approval Letter [33]	Decision Summary [34]

System			
Proteus Personal Monitor Including Ingestion Event Marker	K113070	Approval Letter [35]	Decision Summary [36]
PORTRAIT TOXIGENIC C. DIFFICILE ASSAY	K113358	Approval Letter [37]	Decision Summary [38]
Verigene® Gram Positive Blood Culture Nucleic Acid Test (BC-GP)	K113450	Approval Letter [39]	Decision Summary [40]
COBAS INTEGRA 800 Tina-quant HbA1cDx Gen.2 assay	K121291	Approval Letter [41]	Decision Summary [42]
xTAG® Gastrointestinal Pathogen Panel (GPP)	K121454	Approval Letter [43]	Decision Summary [44]
Quantitation of Organophosphate Metabolites in Urine by LC/MS/MS	K122282	Approval Letter [45]	Decision Summary [46]
AXIOS Stent and Delivery System	K123250	Approval Letter [47]	
X-ray Attenuating Cream	K123422	Approval Letter [48]	Decision Summary [49]
Vysis EGR1 FISH Probe Kit	K123951	Approval Letter [50]	Decision Summary [51]
Illumina MiSeqDx Platform	K123989	Approval Letter [52]	Decision Summary [53]
FerriScan R2-MRI Analysis System	K124065	Approval Letter [54]	Decision Summary [55]
VITEK®MS	K124067	Approval Letter [56]	Decision Summary [57]
NeoTract UroLift System, Model REF UL400	K130651	Approval Letter [58]	Decision Summary [59]
Xpert MTB/RIF Assay	K131706	Approval Letter [60]	Decision Summary [61]
MiSeqDx Universal Kit 1.0	K133136	Approval Letter [62]	Decision Summary [63]

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Links:
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