Evaluation of Automatic Class III Designation (De Novo) Decision : K124065 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 certain new devices that had automatically been placed in Class III due to lack of a predicate.

The De Novo process applies to low and moderate risk devices that have been classified as class III because they were found not substantially equivalent (NSE) to existing devices. Applicants who receive this determination may request a risk-based evaluation for reclassification into class I or II within 30 days of receipt of an NSE determination. Devices that are classified through the De Novo process may be marketed and used as a predicate for future Premarket Notification [510(k)] submissions.

FDA has begun releasing De Novo Summary documents for devices granted market authority 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 of the decision to grant a de novo petition. The Summary outlines how FDA determined that the device for which a petition is granted is low to moderate risk and that general and/or special controls provide reasonable assurance of safety and effectiveness. The De Novo Summary also serves as a resource on the types of information necessary to support substantial equivalence for device manufacturers that may wish to use the de novo 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]	
Zeltiq™ Dermal Cooling Device	K080521	Approval Letter [2]	
Erchonia ML Scanner	K082609	Approval Letter [3]	
NuMED NuCLEUS and NuCLEUS-X BAV Catheters	K082776	Approval Letter [4]	Decision Summary [5]
Hem-Avert Perianal Stabilizer	K083692	Approval Letter [6]	
RIDASCREEN Norovirus 3rd Generation EIA	K093295	Approval Letter [7]	

Prostate Mechanical Imager	K093579	Approval Letter [8]	Decision Summary [9]
LipiFlow Thermal Pulsation System	K093937	Approval Letter [10]	
Steris Verify Spore Test Strip for S40	K100049	Approval Letter [11]	Decision Summary [12]
InBios DENV Detect IgM Capture ELISA	K100534	Approval Letter [13]	Decision Summary [14]
Widex C4-PA Wireless Air-Conduction Hearing Aid	K101699	Approval Letter [15]	Decision Summary [16]
Aptus Endovascular Suturing System	K102333	Approval Letter [17]	Decision Summary [18]
ImmunoCAP Tryptase	K103039	Approval Letter [19]	Decision Summary [20]
Percutaneous Surgical Set with 5 mm or 10 mm Attachments	K110431	Approval Letter [21]	Decision Summary [22]
STRATIFY JCV Antibody ELISA	K112394	Approval Letter [23]	Decision Summary [24]
Proteus Personal Monitor Including Ingestion Event Marker	K113070	Approval Letter [25]	Decision Summary [26]
PORTRAIT TOXIGENIC C. DIFFICILE ASSAY	K113358	Approval Letter [27]	Decision Summary [28]
Verigene® Gram Positive Blood Culture Nucleic Acid Test (BC-GP)	K113450	Approval Letter [29]	Decision Summary [30]
xTAG® Gastrointestinal Pathogen Panel (GPP)	K121454	Approval Letter [31]	Decision Summary [32]
FerriScan R2-MRI Analysis System	K124065	Approval Letter [33]	Decision Summary [34]

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http://www.mdtmag.com/news/2013/02/evaluation-automatic-class-iii-designation-de-novo-decision-k124065-added?qt-video_of_the_day=0

Links:
[1] http://www.accessdata.fda.gov/cdrh_docs/pdf8/K080377.pdf
[2] http://www.accessdata.fda.gov/cdrh_docs/pdf8/K080521.pdf
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