Food and Drug Administration (FDA)
Glossary

De Novo – There are two pathways to "De Novo" device designation with FDA:
The first pathway is to classify new devices into Class I or II that had automatically been placed in Class III after receiving a Not Substantially Equivalent (NSE) determination in response to a 510(k) submission.

The second pathway, once a sponsor determines that there is no legally marketed device upon which to base a determination of substantial equivalence, may request FDA to make a risk-based classification of the device into Class I or II without first submitting a 510(k).

Investigational Device Exemption (IDE) – Allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification 510(k) submission to FDA.

Medical device classification – Medical devices are classified into Class I, II, and III. The three classes are based on the product risks and the level of regulatory control needed to ensure safety and effectiveness. Class I medical devices are the lowest risk for patients and Class III devices have the highest risk.

Request for Designation (RFD) – This written submission to FDA generally requests a determination of the regulatory identity or classification of a product as a drug, device, biological product, or combination product, and which area of FDA will regulate the product, depending on its designation.

Request for Reconsideration (RFR) – An FDA procedure to consider an applicant's concern or disagreement. The sponsor is asked to include information to help explain the nature of the scientific and/or regulatory issue to help FDA to determine the next steps.

510(k) Premarket Notification – A premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to premarket approval.