Appendix A – De Novo Evaluation Criteria

The De Novo request provides a marketing pathway to classify medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. The ProSense System was considered eligible for De Novo classification, because there is no legally marketed predicate device with similar technology intended specifically for the treatment of patients with early stage, low-risk breast cancer.

De Novo classification is a risk-based classification process. Devices that are classified into class I or class II through a De Novo classification request (De Novo request) may be marketed and used as predicates for future premarket notification [510(k)] submissions, when applicable.

After review of a De Novo request, the FDA will make a final decision, either to grant or decline (21 CFR 860.260). If the data and information provided to the FDA demonstrate that general controls or general and special controls are adequate to provide reasonable assurance of safety and effectiveness, and the probable benefits of the device outweigh the probable risks, then the FDA intends to grant the De Novo request and establish a new classification regulation for the new device type.

Generally, the FDA will decline a De Novo request if:

- General controls or general and special controls are insufficient to provide reasonable assurance of safety and effectiveness of the device; or
- The data provided in the De Novo request are insufficient to determine whether general controls or general and special controls can provide a reasonable assurance of safety and effectiveness of the device; or
- The probable benefits of the device do not outweigh the probable risks.

If the De Novo request is declined, the device remains in class III and the requester may not legally market the device. The FDA will issue a written order to the requester identifying the reasons, which can include lack of performance data that warrant declining the De Novo request. The requester generally should either submit an application for premarket approval under section 515 of the FD&C Act or collect additional information to address the issues and submit a new De Novo request that includes the additional information.

See FDA guidance Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications for additional information regarding benefit-risk determination in the context of a De Novo Classification request (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-when-making-benefit-risk-determinations-medical-device-premarket-approval-and-de).