Elexes

De Novo Summary Usage Checklist

- [ ] Confirm that the FDA product code aligns with your device type
- [ ] Verify that the intended use and indications for use are comparable
- [ ] Review the device classification assigned under the De Novo pathway
- [ ] Compare technological characteristics with your device design
- [ ] Identify all applicable general controls
- [ ] Review each special control listed in the decision summary
- [ ] Assess how special controls impact design, testing, and labeling
- [ ] Review required non-clinical bench performance testing expectations
- [ ] Check whether clinical data was required or waived
- [ ] Review risk mitigations expected by the FDA and evaluate their applicability to your device
- [ ] Review software, cybersecurity, or usability controls, if applicable
- [ ] Review biocompatibility and materials considerations
- [ ] Evaluate labeling, instructions for use, and warning requirements
- [ ] Plan additional testing or justification to address gaps if there are technological differences with respect to your device
- [ ] Document how the De Novo summary supports your regulatory rationale