# Regulatory Summary

The benefit of starting with ovulation testing is that the regulatory barriers are relatively low. This is the most clear and well defined path to get a diagnostic product into people’s homes.

According to regulation 862.1485, LH tests in urine or serum are Class 1 and exempt from premarket notification. The associated product code is NGE, which contains almost all the ovulation tests currently on the market including Clearblue and Easy@Home. We have confirmed that we also fall under this product code by having two separate regulatory consultants complete a regulatory assessment (K2 consulting and HP&M. The resulting regulatory path is shown below:

Complete user testing for CLIA application.

File pre-submission to confirm CLIA requirements.

Register establishment with the FDA.

Launch Product

File CLIA application.

Receive CLIA waiver.

Implement QMS

Q2 2022

Q1 2022

Q1 - Q2 2022

Before Q3 2021 (depending on FDA availibility)

If CLIA Application is Required

If CLIA Application is Not Required