



OVERVIEW

We provided the manufacturing for fertility monitoring devices (FDA class 1 medical device) for a renowned women's health diagnostic producer that needed a low cost, high quality contract manufacturer. The company was aiming for new markets including Asia.

CHALLENGES

- Required well-developed quality and documentation system
- Special emphasis on product tracking and traceability
- Turnkey manufacturing partner with capability for compliance of recognized medical standard
- Short implementation time

SERVICES PERFORMED

- Design for manufacturability
- Agency/compliance testing
- Product traceability and documentation control

RESULTS

- Successful launch of device in short time frame, meeting customer's quality and traceability standards