



# Compliant Clinical Build

## Contract Manufacturing

### FDA / ISO13485 Registered

#### Compliant Clinical Build Service:



HDA offers Compliant Clinical Production services at our FDA, FDB, and ISO-13485 registered facility. This service is a hybrid of engineering-based transfer to manufacturing and procedure-based assembly and test services that is overseen and conducted by experienced engineers, technicians, and support personnel.

Perfect for supporting a 510(k) submission, we produce small numbers of pre-production or Beta Prototype devices that are fully compliant with all specifications, documentation, quality, and traceability and performance requirements.



We also provide DHF remediation support, completing, correcting or creating documentation as necessary to ensure that your device can be trusted in clinical use and that you are ready for your FDA filing.

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#### Contract Manufacturing:



Our contract manufacturing services include:

- Box Build
- High Complexity
- High Value-Add
- Low-Mid Volume
- Compliant Pilot Builds
- Optical, Electromechanical, RF
- 100% Final Test
- Complete Fulfillment / Repair



HDA provides full service medical product design and contract manufacturing, and has been creating world class products for over 35 years. We support your needs for R&D, design, compliance, production and product support. Our multidisciplinary team provides the attention and responsiveness you need to move your idea into production. HDA is ISO13485, FDA and California FDB registered.

