



Devicix

Engineering the Future of Medicine

Orthopedic Products

Case Study

TITANIUM TRAUMA IMPLANT SYSTEM

DGIMED ORTHO required a new titanium intra-medullary nail fixation device (IMFD) including a complete set of associated orthopedic instruments.

Devicix was engaged to create new orthopedic implants, and work with DIGIMED medical advisors to develop optimal orthopedic instruments.

Medical product design by Devicix:

- Concept to 510k submission in 11 months
- Class II medical device, FDA approved
- Complete medical product design history file DHF
- Orthopedic implant (nail) anatomical optimization
- Detailed design of all orthopedic implants: nail, screws and end caps
- Design of complete set of orthopedic instruments
- Testing of orthopedic implants (nails and screws) per ASTM standards
- Design verification of orthopedic products
- Cadaver tests for design, instructions for use (IFU), and human factors engineering (HFE) validation

