July 22, 2020
NOTICE TO THE PUBLIC
Request for Quotation (RFQ)

The Food and Drug Administration (FDA) seeks competitive offers which will be awarded via a purchase order.

Project Title
Service Contract for Machining Orthopedic Implants

Period of Performance

One (1) Year from Award Date

Statement of Work (SOW)
Service Contract for Machining Orthopedic Implants

Background
The FDA requires orthopedic implants for investigating the intra-operative failure mechanisms in orthopedic implants. Failure of these implants during a surgical procedure (intra-operative scenario) can cause the fractured pieces of these implants to enter sensitive anatomical areas that can cause other surgical complications along with increased surgical costs and time.

Objectives
The FDA will purchase manufacturing (machining) services to produce orthopedic implants for investigating the intra-operative failure mechanisms in these orthopedic implants.

FDA will be paying for all the shipping costs.
FDA will be providing the PEEK material to the contractor.

The vendor shall be required to manufacture the Orthopedic Implants from Polyethylene Ether Ketone (PEEK) to the required specifications listed in the below FDA Orthopedic Implant engineering drawings.

- Orthopedic Implant Drawing - TLIF PEEK CAGE - 36 x 10 x 8.pdf
- Orthopedic Implant Drawing -TLIF-36 x10 x 8mm.pdf

Scope
The orthopedic implants will be utilized to determine the mechanisms of intra-operative device failures by gathering clinical data and to develop an in vitro test method for

simulating such device failures. This research will help link clinical outcomes with pre-clinical testing which can be used to assess whether various surgical techniques and design characteristics can be improved/modified to reduce the risks of device failure and complications during orthopedic surgery.

Tasks and Salient Characteristics

The vendor shall provide machined orthopedic implants to the required tolerance listed on the FDA Orthopedic Implant engineering drawings:

- Orthopedic Implant Drawing - TLIF PEEK CAGE - 36 x 10 x 8.pdf
- Orthopedic Implant Drawing -TLIF-36 x10 x 8mm.pdf

FDA Orthopedic Implant	Required Quantities
Orthopedic Implant Drawing - TLIF PEEK CAGE - 36 x 10 x 8	120
Orthopedic Implant Drawing -TLIF-36 x10 x 8mm	120

The vendor with the following:

- Shall have extensive experience with machining orthopedic medical devices
- Shall be able to manufacture orthopedic implants based on the given engineering drawings and supplied material
- Shall machine the parts to ISO 9001 quality standard
- Shall have 10 years of experience with machining polyethylene ether ketone (PEEK) material
- Shall have experience in handling the tolerances listed in the FDA Orthopedic Implant drawings
- Shall listed estimated completion date after receiving the PEEK material from the FDA.

Delivery

The vendor shall coordinate the Program Manager for all shipping and handling.
FDA will be paying for all the shipping costs.

Government-Furnished Property, Material, Equipment, or Information (GFP, GFM, GFE, or GFI)

FDA will be providing the PEEK material to the contractor for use in the manufacturing of the orthopedic implants.
The Program Manager (PM) will work with the contractor to determent the disposition of any remaining FDA provided PEEK material.
The FDA will pay for Excess PEEK material returned to the FDA.

Security

Not Applicable

Travel

Not Applicable

Special Material Requirements

FDA will be providing the PEEK material to the contractor for use in the manufacturing of the orthopedic implants.
The Program Manager (PM) will work with the contractor to determent the disposition of any remaining FDA provided PEEK material.
The FDA will pay for Excess PEEK material returned to the FDA.

The Expected delivery is less than 12 weeks after receiving the FDA PEEK material

Place of Performance

Work to be completed at the Contractor facility.

All quotes must be received by 10:00 a.m., Eastern Standard Time on July 28, 2020 via email to Linda Troutman at Linda.Troutman@fda.hhs.gov. When submitting the quotation please include the RFQ#1231889 in the subject line. The FDA intends to make an award immediately after the response date of this notice. The award will be made in accordance with FAR Part 13, Simplified Acquisition.