DESCISION TREE FOR MANUFACTURED & FABRICATED DEVICE PROJECTS

IRB REVIEW

1. Does your project involve “human subjects”?
   - YES
   - NO

2. Is it “research”?
   - YES
   - NO

IRB submission may be required. Contact the IRB office for consultation.
If IRB submission is needed, allow for approximately 4 weeks for review.

DEVICE SAFETY REVIEW

1. Are you manufacturing or fabricating a new device?
   - YES
   - NO
   OR
   Are you modifying a commercially available device?

2. Will the device be transferred to non-Marquette individual (i.e., non-faculty, staff, student)?
   - YES
   - NO

3. Will the device be used for medical treatment under the supervision of a health care professional?
   - NO
   - YES

Device Safety Review submission is required. Allow for 2 weeks for review/inspection.