STANDARD OPERATING PROCEDURE

Title: Manufactured Material Quality Assurance Procedure

Effective Date: _____

Approvals (Signature and Date):

_____	_____	_____
Responsible Department Head	Technical Authority	QA/QC

1. PURPOSE

1.1 To describe the method for assuring the identity and fitness for use of manufactured materials.

2. SCOPE

2.1 This procedure applies to all materials manufactured for use internally, clinical research, and for those intended for commercial sale.

2.2 This procedure does not apply to materials procured from external sources. Refer to 09-0003-SOP-1.0.

3. RESPONSIBILITY

3.1 Quality Control personnel are responsible for procuring samples as appropriate, performing required inspection and testing, and documentation of inspection including materials disposition labeling.

3.2 Manufacturing personnel are responsible for notifying QC of material availability and status.

3.3 Quality Control personnel are responsible for notifying Materials Control of final disposition of material.

4. REFERENCES AND APPLICABLE DOCUMENTS

4.1 09-0003-SOP-1.0, Raw Material Quality Assurance Procedure

4.2 09-0004-SOP-1.0, Discrepancy Reporting Procedure

4.3 09-0015-SOP-1.0, Material Review Board

4.4 09-0074-SOP-1.0, QC Sampling Techniques

4.5 Applicable PNS, Part Number Specifications

4.6 09-0084-SOP-1.0, QC Test Failure, Repetition and Investigation Rules

4.7 12-0012-SOP-1.0, Lot Number Assignment

4.8 12-0014-SOP-1.0, Production Documentation Flow

4.9 09-0006-SOP-1.0, Device History Record

5. MATERIALS AND EQUIPMENT

5.1 Quality Control status labels (i.e., Approval and Rejected labels)

5.2 Manufacturing status labels (i.e., Quarantine labels)