



CONFIDENTIAL – FOR ADDRESSEE ONLY

To Whom It May Concern,

The Stimulan Bullet Mat and Introducer, Product Number 660-001, is a Class I device and is therefore exempt from needing the premarket notification (510k) procedure.

The Stimulan Bullet Mat and Introducer is an Orthopaedic Manual Surgical instrument as defined by the Electronic Code of Federal Regulations: Title 21 – Chapter I – Subchapter H – Part 888 – Subpart E - §888.4540.

Please contact me if I can be of further assistance.

Best regards,

A handwritten signature in blue ink, appearing to read "Kathleen Moon", written over a faint horizontal line.

Kathleen Moon  
Compliance Manager  
Compliance Department