



SOLUBLE SYSTEMS, LLC MEMORANDUM

FROM: MICHAEL WEBER, DIRECTOR OF R&D / QA
SUBJECT: THERAGAUZE™ FDA CLASS I EXEMPT STATUS
DATE: 3/4/2009

Soluble Systems, LLC product, TheraGauze™, has been designated FDA Class I exempt, under regulation #21CFR, Product code §878.4022. This can be confirmed by accessing FDA Device Registration number for TheraGauze™ which is: E673655.

Consistent with the TheraGauze™ Class I exemption status, all toxicity, cytotoxicity, and sensitivity testing has shown no adverse effects of the product.

