To: Rouss, Gino[Gino.Rouss@smith-nephew.com]
Cc: Goode, John[John.Goode@fda.hhs.gov]
From: Goode, John
Sent: Fri 18/12/2009 10:25:50 PM
Subject: K093095 S&N Birmingham Hip (BH) Modular Head System - List of Deficiencies placing the document on Hold
K093095.SN BH ModularHead mm list of deficiencies.DOC

Smith & Nephew, Inc.

Orthopaedic Division

c/o Mr. Gino Rouss, M.S.

Manager, Regulatory Affairs

1450 Brooks Road

Memphis, Tennessee 38116

Based on my review of K093095, dated September 30, 2009 and received October 1, 2009, I cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information provided. To complete the review of your submission, please address the items that are attached in a WORD document in this e-mail. Once we receive your response, our review will continue. It would be helpful if, when you send your response to the document mail center, that you also send me an electronic copy of your response.

<<K093095.SN BH ModularHead mm list of deficiencies.DOC>>

If you need any additional clarification on these items, please let me know.

Thanks,

John S. Goode

Orthopedic Joint Devices Branch

(301) 796-6407

John S. Goode

Reviewer, Orthopedic Joint Devices Branch (OJDB)

FDA/CDRH/ODE/DSORD

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