K962133 AUG - 1 1996

SECTION 14 SMDA SUMMARY for Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the written requirements of SMDA 1990 and 21 CFR 807.92

SAFETY AND EFFECTIVENESS OF EXPANDACELL INJECTO-PAK FOAM PACK FOR ADMINISTRATION OF LIQUID MEDICATION AND HYDRATING FOR THE SINUS

No specific medication is mentioned. The physician will choose medication indicated.

This proposed change to an already approved and marketed device does in no way alter the safety and effectiveness of this medical device. The Expandacell Sinus Pack K935724/S1, Expandacell Injecto-Pak, K954845, and the Expandacell Injecto-Pak K960228 have a proven track record that establishes this product line as safe to the post-operative nasal or post-operative sinus surgery patient. The modification of adapting this product for use in the sinus does not change the safety or effectiveness of this device.

The proposed product is identical in intended use, materials, anatomical sites, target population, physical safety, biocompatibility and performance to the predicate devices stated.

The Toxic Shock issue has been addressed in previous 510(k) applications and this product line addresses this issue on its instructions. Appropriate warning and directions are given for symptoms and appropriate care.

Sarah Maxwell Lake

Signature

May 22, 1996

Date

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