

TEST RESULT CERTIFICATE

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07 1306 NII	Ductor Number	Not Supplied by Spansor	PO Number
10/12/2007	Report Date	Kimberly Mccall	Contact
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10/5/2007	Technical Completion	401 North Raddant Road	
10/3/2007	Technical Initiation	Cyberbond	Sponsor

Test Article Apollo 2075	Apollo 2075
Lot/Batch # 44187F	44187F
Study	Agar Diffusion Test – ISO
Comments None	None

Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials. Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity. ISO 10993-12, 2002, Biological REFERENCES: The study was conducted based upon the following references: ISO 10993-5, 1999, Biological

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories

allowing diffusion of leachable chemicals from the test article, with a layer of agar stained with a vital dye (neutral red). article showed greater than a Mild Reactivity (Grade 2). Grade 4 (Severe reactivity). The test article met the requirements of the test if none of the cultures exposed to the test cultures were incubated at 37 ± 1 °C, in a humidified atmosphere containing $5 \pm 1\%$ carbon dioxide, for 48 hours. (Negative Control Plastic) control articles were prepared to verify the proper functioning of the test system. The test article was applied directly to the surface of the agar, in triplicate. Positive (Buna-N-Rubber) and negative culture, in response to the test article was determined. The monolayer was protected from mechanical damage, while GENERAL PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell Biological reactivity (cellular degeneration and malformation) was rated on a scale from Grade 0 (No reactivity) to

observation. observation. Moderate signs of reactivity (Grade 3) were observed for the positive control article at the 48 hour of reactivity (Grade 0) were exhibited by the cell cultures exposed to the negative control article at the 48 hour RESULTS: Mild signs of reactivity (Grade 2) were exhibited by the cell cultures exposed to the test article. No signs

CONCLUSION: The test article is considered non-cytotoxic and meets the requirements of the Agar Diffusion Test, ISO 10993-5 guidelines

AUTHORIZED PERSONNEL:

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