



Landos Inc.

A SUBSIDIARY OF GROUP LANDANGER CAMUS

K960642

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8 - SUMMARY OF SAFETY & EFFECTIVENESS

MANUFACTURER IDENTIFICATION	Landanger-Landos Z.I. La Vendue BP 88 52003 Chaumont Cedex France
ESTABLISHMENT REGISTRATION NUMBER	9007981
SPONSOR IDENTIFICATION	Jean-Paul Burtin, C.E.O. Landos, Inc. 100 Lindenwood Drive Malvern, PA 19355 Phone: (610) 644-4670 Fax: (610) 644-4429
SPONSOR ESTABLISHMENT REGISTRATION NUMBER	2530066
OFFICIAL CONTACT PERSON	Norman F. Estrin, Ph.D., RAC President Estrin Consulting Group, Inc. 9109 Copenhaver Drive Potomac, MD 20854 Phone: (301) 279-2899 Fax: (301) 294-0126
PROPRIETARY NAME	Nancy Nail™
COMMON NAME	Intramedullary Elastic Nail

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CLASSIFICATION NAME AND REFERENCE	FDA has classified <i>smooth or threaded metallic bone fixation fastener</i> in Class II 21 CFR Section 888.3040. The Nancy Nail™ is classified as a flexible, metallic bone fixation pin.
PRODUCT CLASSIFICATION CODE	87 HTY
PROPOSED REGULATORY CLASS	Class II
PANEL CODE	87 OR
INTENDED USE	The intended use for the 450mm Nancy Nail™ is as a temporary implant to aid in the healing of long bone diaphysis fractures. It is intended for children above 4 years of age and below 65kg. The 100mm Nancy Nail™ is designed for small long bone fractures with a long diaphysis, such as carpal or tarsal bones.
DESCRIPTION	The Nancy Nail™ is a titanium alloy pin, available in two lengths: 450mm and 100mm. The 450mm is available in five diameters: 2.0, 2.5, 3.0, 3.5, 4.0. The 100mm has a diameter of 1mm.
PREDICATE DEVICES	Kirschner's Wire & Steinman Pin Howmedica's Rush Nail