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Dockets Management Branch (HFA-305),  
Food and Drug Administration,  
5630 Fishers Lane, rm 1061  
Rockville, MD 20852  
United States

Uppsala, Sweden, 2002-09-04

Re: Docket No. 01P-0120

Dear Sir/Madam,

With reference to the invitation to submit information on this topic, please find enclosed a brochure of Hemaport<sup>®</sup>. This is a novel, needle-free, device used for vascular access in hemodialysis patients. This clinical situation normally involves frequent use of large-bore cannulas in high-risk patients.

The device is presently used in a limited number of patients in Europe, prior to commercial launch. The device is CE-marked and it is our ambition to arrange a meeting with FDA within shortly to discuss the regulatory pathway for this product into the US market.

This information was sent to you in order to inform you about this emerging technology, eliminating the use of needles in this particular clinical situation.

For further information, we are at your disposal.

Sincerely,

A handwritten signature in black ink, appearing to read "Anders Nilsson".

Anders Nilsson, MD, PhD  
General Manager

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