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3/29/00

Pattyn Karen  
O.L.Vrouw-Hospital  
Pharmacy  
Moorselbaan 164  
9300 Aalst  
Belgium

Docket No.00D-0053, Dockets Management Branch  
Division of Management Systems and Policy,  
Office of Human Resources and Management Services  
Food and Drug Administration  
5630 Fishers Lane, (HFA-305), Room 1061  
Rockville, MD 20852  
U.S.A.

Aalst, 20/03/2000

Dear,

I have a question about the document "REPROCESSING AND REUSE OF SINGLE-USE DEVICES, Review Prioritization Scheme, released on 8 February 2000".

**Example 3 is about cardiac ablation catheter.**

Evaluating the infection risk, the answer to question 3 is, that cardiac ablation catheters do have features that could impede thorough cleaning and adequate sterilization. I 'd like to have more information about those features.

Evaluating the risk of inadequate performance there exist significant post-market data that suggest that the reprocessed cardiac ablation catheter may present an increased risk of patient injury. Can you give me more information about this literature.

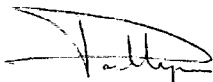
My phone number is: 00 32 53 / 72 42 96

My fax number is: 00 32 53 / 72 45 89

E-mail: karen.pattijn@olvz-aalst.be

or: karen.pattyn@wanadoo.be

Hoping for an answer , yours sincerely,



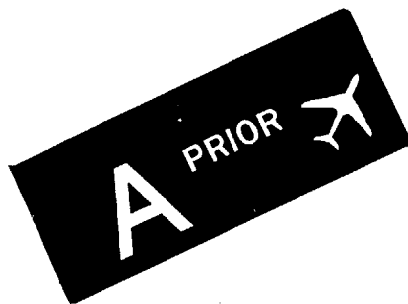
Pattyn Karen

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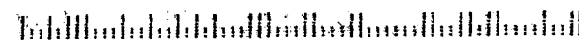
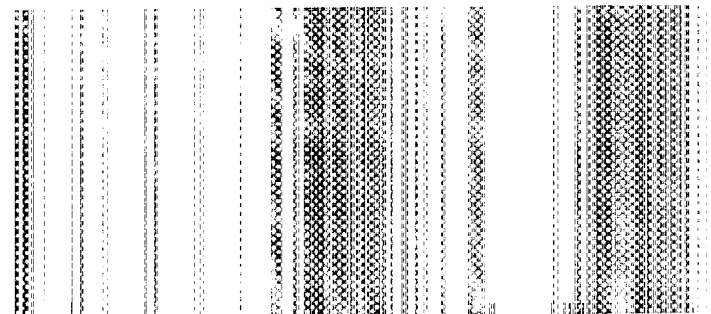
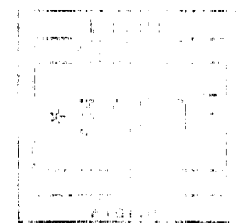


ZIEKENHUIS AALST  
MOORSELBAAN 164  
9300 AALST  
BELGIUM



509

9300 AALST



Apoteker DE SMET  
O.L.Vr. Ziekenhuis  
Moorsebaan 164  
9300 AALST  
Belgium