



August 16, 2016

Tomas Herrera  
U.S. Nuclear Regulatory Commission  
Source Safety and Security Branch  
Office of Federal and State Materials & Environmental Management Programs  
Mail Stop T:8F3  
Washington, DC 20555

RE: NR-0469-D-114-S

Dear Tomas;

The manufacturer of the microSelectron, model 106.990, is in the process of implementing UDI barcodes on the product labels.

Based on these changes, please amend the Sealed Source and Device Registry, NR-0469-D-114-S, with the updated labels as per the attached document *microSelectron-UDI label proposal*.

Should you have any further questions or need additional information, please feel free to contact me at 770-670-2518 or via email at [debra.bensen@elekta.com](mailto:debra.bensen@elekta.com).

Sincerely,

A handwritten signature in cursive script that reads "Debra L. Bensen".

Debra L. Bensen, RSO  
Regulatory Affairs

Enclosures: *microSelectron-UDI label proposal*

# UDI label update of the microSelectron system

Proposed new labels:

microSelectron 6CH 115V

**Nucletron**

**microSelectron Digital**

For brachytherapy. Radionuclide: Ir-192 Max. Activity: 518 GBq

REF 106080802-05 Mains Supply: 4A/100-115 Vac

Part of 106990 Power Input: 370 W

SN 10 158 Mains Frequency: 50/60 Hz

120 Kg Fuse Type: MDQ

2016-07-18 Fuse Rating (A slow): 4A/250 Vac

Nucletron B.V., Waardgelder 1, 3905 TH Veenendaal, The Netherlands

CE 0344

(01) 0871 721 3020467  
(11) 1160718  
(21) 10 158  
(240) 106990

150908-02

microSelectron 30CH 115V

**Nucletron**

**microSelectron Digital**

For brachytherapy. Radionuclide: Ir-192 Max. Activity: 518 GBq

REF 106080C02-05 Mains Supply: 4A/100-115 Vac

Part of 106990 Power Input: 370 W

SN 10 237 Mains Frequency: 50/60 Hz

120 Kg Fuse Type: MDQ

2016-07-18 Fuse Rating (A slow): 4A/250 Vac

Nucletron B.V., Waardgelder 1, 3905 TH Veenendaal, The Netherlands

CE 0344

(01) 0871 721 3020467  
(11) 1160718  
(21) 10 237  
(240) 106990

150908-02

microSelectron 18CH 115V

**Nucletron**

**microSelectron Digital**

For brachytherapy. Radionuclide: Ir-192 Max. Activity: 518 GBq

REF 106080D02-05 Mains Supply: 4A/100-115 Vac

Part of 106990 Power Input: 370 W

SN 10 409 Mains Frequency: 50/60 Hz

120 Kg Fuse Type: MDQ

2016-07-18 Fuse Rating (A slow): 4A/250 Vac

Nucletron B.V., Waardgelder 1, 3905 TH Veenendaal, The Netherlands

CE 0344

(01) 0871 721 3020467  
(11) 1160718  
(21) 10 409  
(240) 106990

150917-02

All shipped systems will have the Distribution label.

Manufactured by:  
Nucletron B.V.,  
Waardgelder 1,  
3905 TH Veenendaal,  
The Netherlands

Distributed in US by:  
Elekta, Inc.,  
400 Perimeter Center Terrace, Suite 50,  
Atlanta, GA 30346

050544-00-00

Extremely Urgent



SSC

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08 17  
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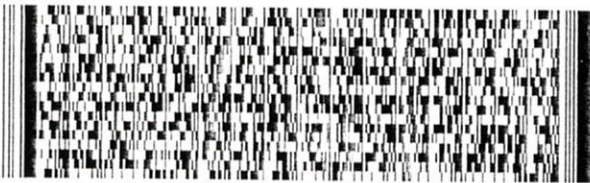
XCN SFA

20852 MD-US IAD

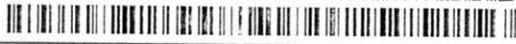
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7770 0136 3786

WED - 17 AUG 3:00P  
STANDARD OVERNIGHT



J152010701001ur



DEPT PO INV (301) 415-7138

REF USELECTRON UDI LABEL AR

ROCKVILLE MD 20852

MAIL STOP T8 E24

11545 ROCKVILLE PIKE

US NRC

TO TOMAS HERRERA

UNITED STATES US

ATLANTA GA 30246

SUITE 50

400 PERIMETER CENTER TERRACE

DEBRA BENSEN

ORIGIN ID: TMAA (410) 913-2162

SHIP DATE: 16AUG16  
ACTWGT: 1.00 LB  
CAD: 105752172/NET3790  
BILL SENDER

544J11/37014FB