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Device Listing Database

Proprietary Name: andropenis

Classification Name: DEVICE, EXTERNAL PENILE

RIGIDITY

Product Code: LKY
Device Class: 2

Regulation Number: 876.5020

Medical Specialty: Gastroenterology

Registered Establishment

Name:

ANDROMEDICAL SL

Registered Establishment

Number:

3006891790

Owner/Operator:

ANDROMEDICAL SL

Owner/Operator Number: 10024070 Establishment Operations: Manufacturer

Database Updated 01/16/2009

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Establishment Registration Database

Establishment:

ANDROMEDICAL SL Calle Procion 7

Madrid, SPAIN 28023

Registration Number: 3006891790

Status: Active

Date Of Registration Status: 2009

Owner/Operator: ANDROMEDICAL SL Calle Procion 7

Madrid, ES-M SPAIN 28023

Owner/Operator Number: 10024070

Official Correspondent:

Eduardo Gomez De Diego

Calle Procion 7

Madrid, ES-M SPAIN 28023 Phone: 034-91-6381899

US Agent:

Ian P Gordon

Senior Vice President EMERGO GROUP

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Database Updated 01/16/2009





Andropenis® is registered with the FDA as an external penile rigidity device intended to create or maintain sufficient penile rigidity for sexual intercourse. **Andropenis**® is not cleared as:

- mechanical penile extenders
- penile enhancement, such as penis enlargement
- treatment of diseases or conditions of the penis with respect to curvature and other penis deformities, e.g., Peyronie's Disease.