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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
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US Agent:

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Database Updated 01/16/2009

Andromedical® has registered the Andropenis® as a Class II device to be used as an external penile rigidity device intended to create or maintain sufficient penile rigidity for sexual intercourse. The 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.

The device is not available for sale in the U.S. for the uses listed above.

