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

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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Database Updated 01/16/2009

Proción, 7
28023 Madrid
España

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.