

Certificate of FDA 510(k) Premarket Notification Clearance

Turkuaz Saglik Hizmetleri Medikal Temizlik Kimyasal

510K number: K101952

Trade Name: Konix® Ultrasound Gel

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic Ultrasonic Transducer

Regulatory Class: II

Product Code: ITX

It is, certifies that there has been an FDA finding of substantial equivalence of the Konix Ultrasound Gel which is a device in compliance with 21 CFR 892.1570 and is now approved for the U.S. market.

Turkuaz Saėlık Hizmetleri, Medikal, Temizlik
Kimyasal Ürünler San. ve Tic. A.Ş.
Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad.
No:45/5 34522 Esenyurt / İstanbul / Türkiye
T +90 212 428 6848 Pbx F +90 212 428 6853
info@turkuazsaglik.com.tr / www.turkuazsaglik.com.tr

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Turkuaz Saglik Hizmetleri Medikal Temizlik Kimyasal

510K number: K130581

Trade Name: Konix® Sterile Gel

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic Ultrasonic Transducer

Regulatory Class: II

Product Code: MUI

It is, certifies that there has been an FDA finding of substantial equivalence of the Konix® Steril Gel which is a device in compliance with 21 CFR 892.1570 and is now approved for the U.S. market.

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Turkuaz Saglik Hizmetleri Medikal Temizlik Kimyasal

510K number: K140506

Trade Name: Joy Drops Natural Personal Lubricant Gel

Regulation Number: 21 CFR 884.5300

Regulation Name: Condom

Regulatory Class: II

Product Code: NUC

It is, certifies that there has been an FDA finding of substantial equivalence of the Joydrops Natural Personal Lubricant Gel which is a device in compliance with 21 CFR 892.1570 and is now approved for the U.S. market.

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No:45/5 34522 Esenyurt / İstanbul / Türkiye
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info@turkuazsaglik.com.tr / www.turkuazsaglik.com.tr