

# RheumApp™

## Medication Reminder Application

Class I Medical Device - Product Code NXQ

## Manufacturer Information

GreenCape Health, Inc.  
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## Device Description

RheumApp is a software-based medication reminder application designed to provide alerts to patients for pre-determined medication dosing schedules through mobile device notification systems.

## Intended Use

RheumApp is intended to provide medication reminders to patients to support adherence to prescribed medication schedules. The device incorporates wireless communication through mobile operating systems to deliver notifications.

## Indications for Use

- For use by patients with serious disease who require assistance in maintaining adherence to prescribed medication schedules.
- For use in the home or community setting.
- Compatible with standard mobile operating systems.

## Warnings

- RheumApp is an assistive tool only and does not replace medical judgment.
- RheumApp is not a medical service. No doctor/patient relationship exists between GreenCape and users of RheumApp.
- Users must consult their healthcare providers regarding their specific medication schedules.
- Medication schedules should only be set according to healthcare provider instructions.
- This device does not guarantee medication adherence.
- Technical issues may affect notification delivery.

## Precautions

- Take physician prescribed medications as directed by your care team.
- Verify notification settings are properly configured on your mobile device.
- Maintain current operating system version on your mobile device.
- Review medication schedule entries for accuracy.
- Internet connectivity required for full functionality

## Operating Instructions

1. Download RheumApp from authorized application stores.
2. Complete user registration.
3. Enter medication schedule as prescribed by healthcare provider.
4. Enable notifications when prompted.
5. Verify reminder settings.
6. Respond to medication reminders as they appear.

## Technical Requirements

- Compatible with iOS and Android operating systems.
- Requires internet connectivity for setup and synchronization.
- Minimum operating system versions: [specify versions].
- Device storage: [specify minimum requirements].

## Maintenance

- Regular application updates required.
- Periodic verification of notification settings recommended.
- Review and update medication schedules as prescribed by healthcare provider.

## Troubleshooting

If notifications are not received:

1. Check device notification settings.
2. Verify internet connectivity.
3. Ensure application is running in background.
4. Contact technical support if issues persist.

## Additional Features

While RheumApp includes additional features for tracking patient-reported outcomes and symptoms, these functions are not part of the medical device functionality and are provided for informational purposes only.

## Regulatory Information

- FDA Listed Class I Medical Device
- Product Code: NXQ
- Establishment Registration: [Pending final FDA registration number]
- Exempt from 510(k) requirements
- Compliant with applicable sections of 21 CFR 820

## Version Information

Software Version: [Current Version] Label Version: 1.0 Date: October 24, 2024