**ASX ANNOUNCEMENT**
**20th November 2024**

# PCK submits application for Adult App FDA De Novo clearance

- **Positive US based validation study results underpin FDA De Novo application**
- **Results are consistent with other previous observational pain tool studies**
- **US Aged Care market is the world's largest – 1.7 million people long-term aged care**
- **Potential FDA clearance for the Adult app would be a major milestone for the Company and provide a predicate for future US entry for PainChek's Infant and broader market segments**

PainChek® Ltd (ASX: PCK) ("PainChek®" or "the Company"), developer of the world's first smart phone-based pain assessment and monitoring application, is pleased to confirm the PainChek Adult App FDA De Novo submission application has been made through the FDA Customer Collaboration Portal (CDRH Portal). This submission follows the positive validation results of the US based validation study ASX announcement on 29th October 2024.

This places PainChek's 2025 US market entry strategy on track. The US Long Term Care market is the largest in the world where 1,700,000 people reside in long-term care facilities, with a potential gross annual recurring revenue value of around $85,000,000 USD for PainChek based the Company's current business model and projected US pricing[1],

"The FDA De Novo is a marketing pathway to classify novel medical devices[2]. Should PainChek Adult successfully obtain FDA regulatory clearance, PainChek® would be the first of its kind FDA-cleared pain assessment tool in the USA specifically designed for aged care residents with moderate to severe dementia who are unable to reliably self-report their pain," added Daffas. "Having commercially proven the Adult App in Australia and the UK we believe we can rapidly repeat the market penetration rates in the USA as the clinical need and desire for this solution is paramount in this significantly large global market."

The Company is also well placed to rapidly penetrate the US and Northern American market given existing partnerships, including PointClickCare, who provide integration access to 1,000,000 aged care beds across USA and Canada.

FDA DE Novo clearance would also provide an important predicate for the PainChek® Infant App and support the expansion of the Adult App into larger US markets, including the larger home care and hospital markets. PainChek also hold a granted US patent that will remain in place until 2038 supporting the first-to-market US position.

PainChek will be submitting the validation data for peer-reviewed journal publication and for presentation at US medical conferences in 2025 as part of the US market entry strategy.



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The FDA states that De Novo application decisions typically require up to 150 days. PainChek has worked closely with the FDA with two previous pre-submissions to clarify the desired clinical end points from the validation study, which should contribute to a timely response from FDA.

1. Reference PCK quarterly June 2024 and FY23/24 Annual Report
2. https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request

This release has been authorized for release by PainChek CEO Philip Daffas.

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**About PainChek®**

PainChek® is the world's first regulatory-cleared medical device for the assessment of pain, enabling best-practice pain management for people living with pain in any environment, from those who cannot reliably self-report their pain, those who can, and for those whose ability to self-report their pain fluctuates.

The PainChek® app is available on smartphones and tablets and combines PainChek's AI pain assessment tool, which intelligently automates the multidimensional pain assessment process, with the Numerical Rating Scale (NRS). This hybrid functionality allows accurate, consistent pain assessment at the point of care, and for care to be considered in PainChek's detailed reporting suite, PainChek® Analytics.

Globally, PainChek® has attained regulatory clearance as a medical device in Australia, Canada, the European Union, New Zealand, Singapore, Malaysia, and the United Kingdom, with FDA review in the United States currently in progress.

PainChek® has contracts with over 1,600 aged care facilities, with more than 7,000,000 digital pain assessments conducted to date, and is trusted by thousands of nurses, carers, and clinicians.

Using PainChek®, facilities can:

- Ensure greater consistency, continuity, and diagnostic certainty in pain assessment and management by decreasing subjectivity and removing unintentional assessor bias
- Streamline the pain assessment process for time-poor carers, with access to the PainChek® tool, the NRS, pain trends, and charting in one solution
- Simplify record-keeping and documentation to demonstrate compliance and support funding claims, with all historical pain assessment data in one place
- Enhance engagement with GPs and allied healthcare professionals

Clinical studies conducted in Australian and UK residential aged care centres have been published in various peer-reviewed journals including the Journal of Alzheimer's Disease. An article in BMC Geriatrics indicates that PainChek® is a valid and reliable instrument to assess the presence and severity of pain in

people with moderate-to-severe dementia living in aged care. Further information on clinical studies can be found here.

PainChek® has successfully supported accurate pain assessment and management for thousands of adults worldwide living with dementia, disability, or other conditions impacting their ability to self-report pain. Building on the success of this technology, the clinically validated PainChek® Infant app identifies and detects six facial action units indicative of pain in infants aged one month to 12 months.

The need for PainChek as a best-practice pain management solution also extends to older people living at home and with access to home care packages that enable long-term home living. PainChek is expanding into home care by partnering with home care and disability service providers.

For more information, visit: https://painchek.com