PainChek
Intelligent Pain Assessment

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PainChek™ receives FDA regulatory guidance

We have received a preliminary response from FDA in relation to our request for PainChek™ FDA classification as per section 513(g) of the Federal Food, Drug, and Cosmetic Act.

The FDA preliminary assessment is that there is no substantially equivalent product to PainChek™ in the US market, and that PainChek™ may be suitable for classification under section 513(f)(2) of the Act to apply for a risk-based De Novo classification. The 510(K) De Novo is a relatively new process for novel devices whose type has not previously been classified.

FDA have advised that we will have to provide clinical performance data to support the pre-market submission. As recommended by FDA, PainChek™ plans to engage with the FDA to review the currently available PainChek™ clinical trial results and identify and agree any additional clinical data required for the De Novo submission. This may require a clinical trial in the USA.

"We are pleased with this preliminary response as the FDA recognise PainChek™ as a novel medical device and we have experience of this process. The added benefits of conducting clinical trials in the USA, prior to commercial launch, includes engaging with major potential clients at an early stage that can accelerate the overall market development in the USA" commented Philip Daffas CEO PainChek Ltd.

Previously we indicated we expected FDA regulatory clearance by the end of calendar year 2018 and this is now unlikely to be achieved. A revised timeline and costing will be developed following completion of the FDA pre-submission process.

The PainChek™ App does already have TGA and CE Mark clearance that provides access to more than 40% of the global market including Europe and Australia, and our commercial focus for FY18 and FY19 is in these markets. This FDA preliminary response does not have material impact on our commercial strategy and business timelines.

For further information contact:

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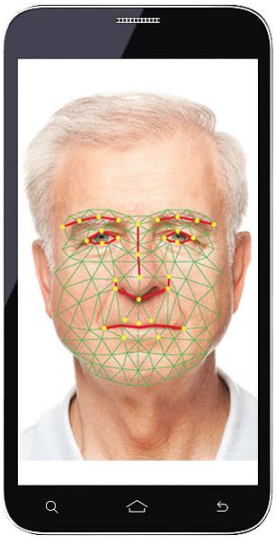
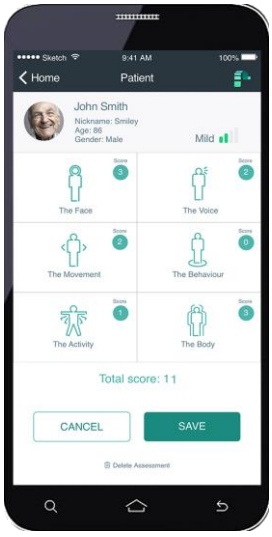
PainChek™
Intelligent Pain Assessment

The PainChek™ Technology:

PainChek™ uses cameras in smartphones and tablets to capture a brief video of the person, which is analysed in real time using facial recognition software to detect the presence of facial micro- expressions that are indicative of the presence of pain.



PainChek™ artificial intelligence assesses facial micro-expressions that are indicative of the presence of pain



PainChek™ six domains of pain assessment that calculates pain severity score

This data is then combined with other indicators of pain, such as vocalisations, behaviours and movements captured to calculate a pain severity score. Due to its speed, ease of use and it's reproducibility, PainChek™ will be able to be used to detect and measure a person's pain, and then further measurements can be used to monitor the effectiveness of pain management.

PainChek™ will be rolled out globally in two phases: first, PainChek™ which is designed for adults who are unable to effectively verbalise their pain such as people with dementia, and second, PainChek™ for Children who have not yet learnt to speak.