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FOR IMMEDIATE RELEASE
September 15, 2014



Invictus Medical Submits Application to FDA, Brands Device ‘Gel Shield™’

Early 2015 Market Launch Anticipated

(SAN ANTONIO, Texas) – Invictus Medical, the San Antonio, Texas-based medical device company dedicated to providing newborns with healthy developmental milestones, today announced it has submitted its application to the Food and Drug Administration in anticipation of marketing the company’s extracranial pressure relief device for newborn infants.

The Food and Drug Administration (FDA) has received the Invictus Medical premarket submission notification [also called a 510(k) submission] for the first clinical indication of its extracranial pressure relief device. Once the FDA has reviewed the 510(k) documentation and cleared the device, the company can begin marketing it immediately.

The 510(k) was filed with a proposed indication for alleviating extracranial pressure due to prolonged immobility. In support of the 510(k) filing, the device has undergone a comprehensive safety validation study at a prestigious and nationally recognized teaching and research hospital in Dallas.

In addition, the United States Patent and Trademark Office has issued a notice of allowance for the mark, “Gel Shield™,” the brand under which the device will be marketed.

Long term, Invictus Medical’s technology interest focuses on combating deformational plagiocephaly (DP), a cranial deformity exhibited in infants resulting from repeated external pressure to one area of the head. Studies have found a significant rise in the incidence of plagiocephaly since the early 1990s. In addition to being a cosmetic issue, DP has been associated with heightened risk for developmental delays in infants and toddlers, according to a study published in Pediatrics in 2013.

“Our mission is to secure healthy early development milestones in newborns by providing innovative products, services and solutions to the healthcare professional and consumer markets,” said Tom Roberts, Invictus Medical President and CEO. “The submission of our 510(k) application, in addition to the notice of allowance for the Gel Shield brand name, moves us substantially closer to fulfilling this mission. We anticipate product commercialization in early 2015.”

Invictus Medical is nearing the close of its Series A round of funding and has raised more than \$4 million to date. The company anticipates securing its Series B funding round in early 2015.

About Invictus Medical

Invictus Medical is a San Antonio, Texas-based medical device company that aims to ensure that children are able to attain their developmental milestones. As evidenced by their award-winning innovations, Invictus Medical has been at the forefront of pediatric care since its founding in 2012. Invictus Medical is a privately held company. For more information about Invictus Medical, please see [www. Invictusmed.com](http://www.invictusmed.com).

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