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ID Chip's Controversial Approval

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A surprise decision by the Food and Drug Administration permits the use of implantable ID chips in humans, despite an FDA investigator's recent public reservations about the devices.

The FDA sent chip manufacturer Applied Digital Solutions a letter stating that the agency would not regulate the VeriChip if it was used for "security, financial and personal identification or safety applications," ADS said Tuesday.

But the FDA has not determined whether the controversial chip can be used for medical purposes, including linking to medical databases, the company added. In the United States, ADS has principally marketed VeriChip as a life-saving tool, saying, for example, that unconscious patients brought to emergency rooms could be scanned to determine their medical histories.

Repeated phone calls to the FDA's press office were not returned Tuesday, and ADS refused to provide the media with a copy of the agency's letter.

The decision comes five months after ADS made international headlines by implanting three members of a Florida family with the VeriChip, which is slightly larger than a grain of rice and emits a 125-kilohertz radio frequency signal that can be picked up by a scanner up to four feet away.

In an interview earlier this month, FDA investigator Wally Pellerite said he was unaware of any implantable device that was not regulated by the FDA. Cosmetic implants -- including breast and penile enhancers -- undergo a rigorous FDA examination to determine their effect on the human body despite having no medical function.

Although ID chips have been used in animals for years, they may have "inherent risks" when used in humans, Pellerite said in the interview.

On Tuesday, Pellerite referred questions to the FDA press office.

"At this point, I can't say anything other than to represent what the official agency opinion is in this matter," he wrote in an e-mail. "Previously I was free to give you both sides of the argument and to point out the pros and cons to each. I am no longer free to do that."

Applied Digital Solutions has gotten into hot water in the past for issuing conflicting

statements to the media and to the FDA about the VeriChip's intended use. In May, the FDA launched an investigation into the VeriChip when the company repeatedly referred to the chip as a medical lifesaver in the media, yet assured officials it was merely an identification device.

Tuesday's press release was also confusing, with ADS repeatedly referring to VeriChip as a medical device despite the fact that the FDA has not ruled whether the chip may be used for health purposes.

ADS president Scott Silverman did not comment on the release, but said he was pleased with the FDA's decision.

"We'll now go into high gear with our sales, marketing and distribution plans in the U.S.," he said, adding that the company would be focusing on the security and ID aspects of the microchip.

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