Zarlink Semiconductor

Presentation to the Federal Communications Commission

April 27, 2009

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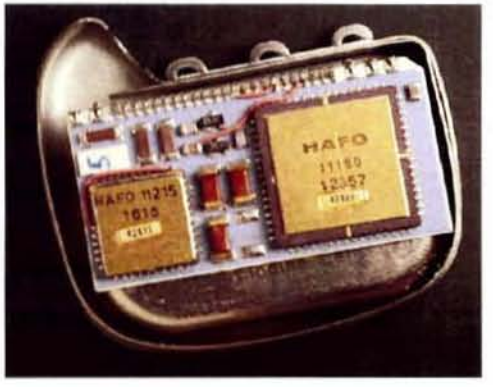
SEMICONDUCTOR

Company Overview
Medical Heritage

- 1973 – Zarlink Semiconductor commenced operations as the semiconductor division of Mitel Corporation
- 2001 – Mitel Semiconductor becomes Zarlink Semiconductor
- Traded as ZL on TSX
- Zarlink's Medical heritage, through its acquisitions, dates to 1954
  - 1976 – introduces first pacemaker chip
  - Delivered >10M pacemaker chips
  - Delivered >50M hearing-aid chips
- Zarlink's RF heritage, through its acquisitions, dates to 1958
  - 2004 – Zarlink releases custom Tx chip to Given Imaging
  - 2006/7 – Zarlink releases ZL70100/101 MICS Transceiver



Fits completely inside the ear canal

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Supplier of Mixed Signal Products

Medical Products

Wireless Technology for Medical Systems

Communication Products

Timing and Voice Enhancement Products for Access, Residential and Enterprise Markets

Optical Interconnect Technologies for Data Centers and Computer Clusters

Optical Products

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Key Customers by Product Group

Communication Products

Nokia Siemens Networks
ZTE 中兴
Alcatel·Lucent
Scientific Atlanta
NORTEL NETWORKS
ARRIS
CISCO
Tektronix
AVAYA
PHILIPS
STARCOM
LINKSYS
Panasonic
MOTOROLA
ERICSSON
Marconi
Huawei Technologies

Medical Products

GIVEN IMAGING
Expanding the scope of GI
Medtronic
Cochlear
STARKEY
ST. JUDE MEDICAL
Boston Scientific
Delivering what's next.

Optical Products

Google
BAE SYSTEMS
Myricom
Tektronix
IBM
JDS Uniphase
PHILIPS
Panasonic
Nokia Siemens Networks

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Why are we here?

- Zarlink Semiconductor applauds the recent Report & Order authorizing the introduction of the MedRadio Service
- Zarlink strongly recommends that the Commission maintain the recently authorized rules, and does not take any action that will undermine the tremendous benefits that will arise from products which comply with these rules
- In that regard, Zarlink firmly opposes the authorization of high duty cycle applications, such as wireless hearing aids, in the MedRadio bands
  - Battery depletion of MedRadio devices
  - Interference with MedRadio devices
- Zarlink supports the introduction of wireless hearing aids in other suitable spectrum

Representative Benefits of MedRadio Wireless Medical Technology

→ Clinical Setting →

Clear sterile field

Reduces infection risk

Eliminates wire entanglement (neonatal)

→ Home Monitoring →

Allows patient mobility

Gets patients home quicker

Greater patient acceptance

Reduces healthcare costs

→ Doctor's Office →

Reduces human error

Increases reliability

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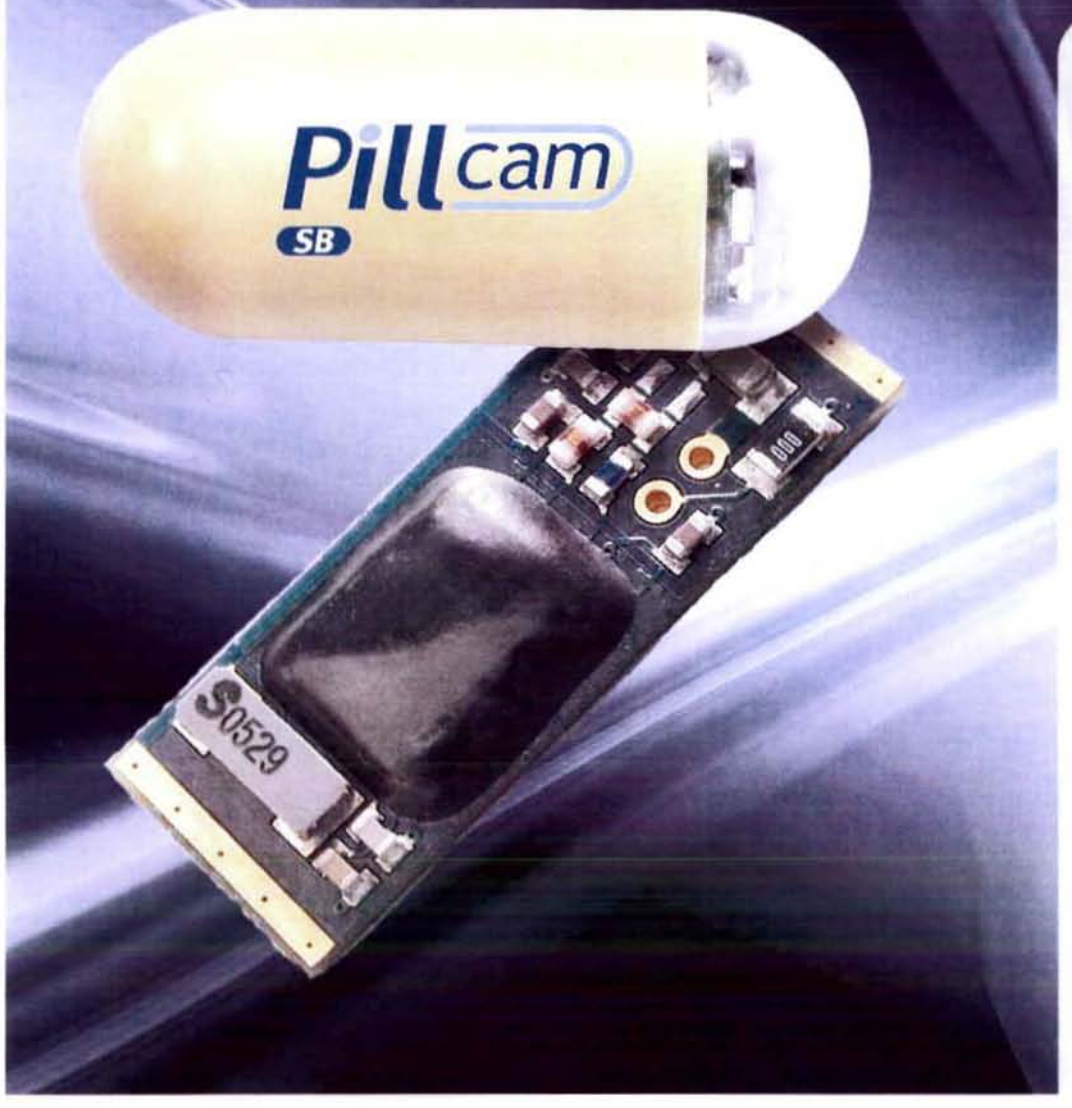
MedRadio Application Examples

- Cardiac Rhythm Management
  - Pacemakers, defibrillators
- Physiological Monitoring
  - Temperature, Blood Pressure, Blood Oxygen, ECG, others
- Parkinson's & Dystonia Therapy
- Epilepsy Management
- Chronic Pain Management
- Obesity Control
- Drug Delivery (diabetes, cancer, pain, others)
- Incontinence Management
- Many others

Wireless Technology for Implanted Medical Communications Systems



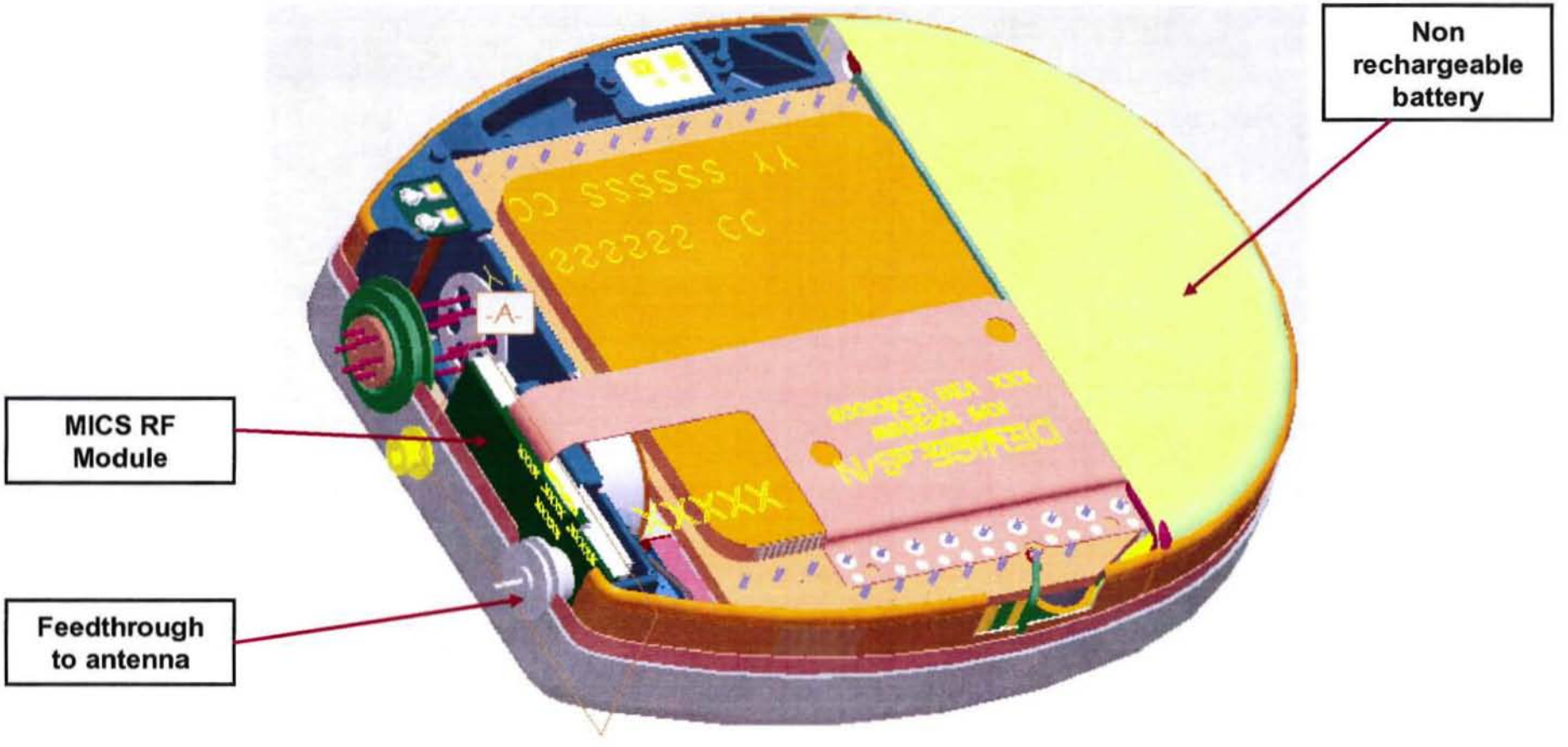
MICS Wireless Chip

- Ultra low-power radio chip for implanted medical devices
- Health and performance data wirelessly transmitted to the physician, without patient intervention
- Applications include pacemakers, defibrillators, neurostimulators

Given Imaging Camera Capsule

- Low-power transmitter chip relays high resolution images from inside the body

MICS RF Module inside a pacemaker



Courtesy: St. Jude Medical

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MICS Applications are Proliferating

ST. JUDE MEDICAL

HV ICDs
(Production)

Merlin.@home

LV Pacemakers
(1H CY09 Launch)

Current™ RF and Promote™ RF

Accent™ and Anthem™

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MedRadio Proliferation

- There have been approximately 500,000 implants of MICS based CRM (Cardiac Rhythm Management) devices to date
  - Increasing at a rate of ~10,000 per month
- There are new applications in late stage development (Deep Brain Stimulation, Pain, Gastric, and others)
  - Include MEDS capability
  - Relying on stability of spectrum rules
- MEDS is expected to deploy similarly to MICS
  - Traditional deployment has started with CRM applications
  - Geometric adoption across multiple applications
  - MedRadio proliferation will accelerate

400MHz Wireless Hearing Aids Will Interfere with MEDS & other devices

- Coexistence of proposed 400MHz wireless hearing aids and MEDS devices is <u>not</u> possible
  - Continuous operation of 400MHz wireless hearing aids will drain MedRadio device batteries prematurely
  - Incompatible receiver sensitivities
  - Incompatible LBT thresholds
  - Large interference range affecting MEDS devices
  - Out-of-Band (OoB) emissions will interfere with adjacent 100kHz channels
- OoB emissions from continuous operation in the top 300kHz of the MEDS band may also interfere with COSPAS / SARSAT
- More suitable spectrum for wireless hearing aids is available

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400 MHz Wireless Hearing Aids Will Drain MedRadio Batteries Prematurely

- MedRadio devices employ a "sniff" mode wake-up scheme to minimize power
- Continuous signals from 400MHz wireless hearing aids will increase processing time and power usage in MedRadio devices
- Detrimental to MEDS device longevity
- Detrimental to MICS device longevity if 400MHz wireless hearing aids operate close to the MICS band
  - Implant batteries are non rechargeable and require highly invasive surgery to replace the device
- Compounding this is the continual requirement for even smaller medical devices with smaller batteries

Incompatible LBT thresholds

- MEDS devices have much higher sensitivity than the proposed 400MHz wireless hearing aids
  - MEDS Sensitivity : better than -100 dBm (100kHz channel) (0 dBi antenna gain in external instrument)
  - Hearing Aid Sensitivity (ON Semi): worse than -84 dBm
  - Due to differing bandwidths (100 kHz vs. 300 kHz) and the low current consumption and very small antenna in hearing aids
- Therefore, the hearing aid cannot detect an existing MEDS communication session.
- Therefore, 400MHz wireless hearing aid LBT is essentially useless

Large Interference Range

- **Minimum potential interference to MEDS devices is at least 24 meters and typically 54 meters**
- **Area of potential interference = 19478 to 98607 ft^2**

MEDS Victim RX Sensitivity (dBm)	Hearing Aid Interferer Separation Distance Required			Conditions
	For -41 dBm Interferer TX ERP (meters)	For -30 dBm Interferer TX ERP (meters)	For -16 dBm Interferer TX ERP (meters)	
-104	54	122	341	Typical conditions as per ETSI TG30 Presentation (TX 3dB BW=100 kHz, C/I=14 dB)
-100	24	54	152	Least interference conditions (TX 3dB BW=200 kHz, C/I=10 dB)

General Model conditions:

1. MCL as per *TG30 Preliminary Hearing Aids Interference Analysis ETSI ERMTG30#21_10r1*
2. Co-channel interference from the hearing aid to the MEDS external victim receiver
3. n = 3.14 propagation exponent for log-normal indoor propagation

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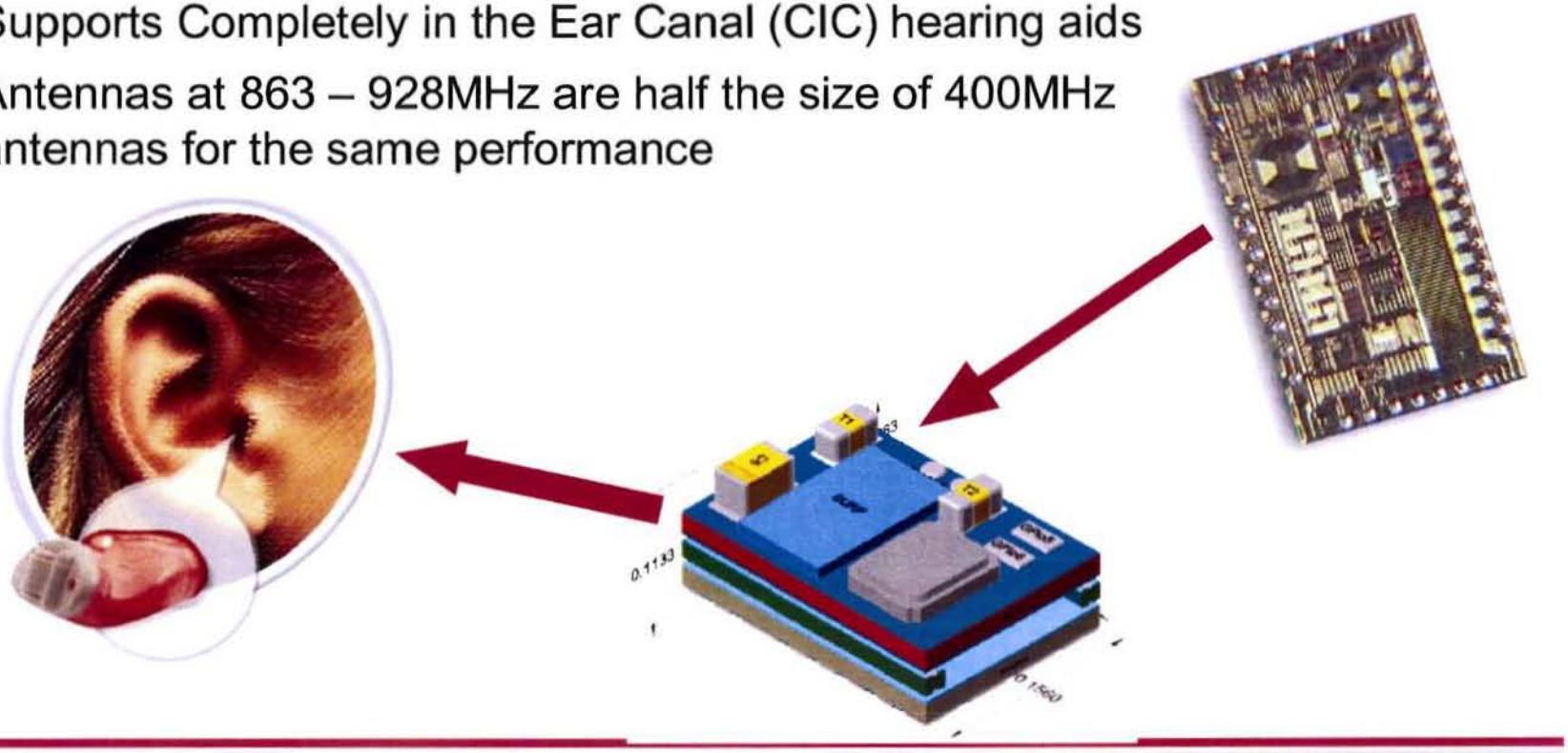
Available RF Spectrum for Wireless Hearing Aids

- **ZL70250 is a custom RF transceiver specifically designed for hearing aid communication**
- **In US, operates at 902 – 928 MHz (ISM) under Part 15.249**
- **In Europe, operates at 863 – 865 MHz**
- **ZL70250 fully supports hearing aid communications including**
  - Bi-directional voice for connection to cell phone
  - Mono-directional full hearing aid bandwidth audio for (i) patient fitting and programming and (ii) music
  - Ear to ear communication for improved hearing aid functions and processing
- **At a range of 5 meters**
- **With a power consumption of 2 mW (1.2V Zinc-Air Cell)**

Available RF Spectrum for Wireless Hearing Aids

Miniature size to fit in HA module

- 3 x 2 mm; 2 external components: crystal and 1 resistor
- Supports Completely in the Ear Canal (CIC) hearing aids
- Antennas at 863 – 928MHz are half the size of 400MHz antennas for the same performance



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European Perspective

- Each EU country has a set of national Interface Regulations, which equipment must meet to be legally used
- In the UK, the applicable IR for all Short Range Devices is IR2030. This calls for equipment in the MedRadio band to meet EN301 839 – which does not allow speech
- Such a device would not meet the UK IR2030 regulation, regardless of a Notified Body opinion under the R&TTED
- Similar prohibitions exist in numerous other EU countries

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Microwave Bands for Wireless Medical Applications

- The European Telecommunications Standards Institute (ETSI) (www.etsi.org) have produced a Systems Reference Document TR102 655 for Low Power Active Medical Implants (LP-AMI) operating in a 20 MHz band within 2360 - 3400MHz
- The frequency range 2300 – 2400 MHz is not available in Europe for medical applications
- The band 2400 – 2483.5MHz is considered to be too widely used to offer the required degree of reliability
- The band 2483.5MHz to 2500MHz could be suitable in Europe and potentially promote international harmonization

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Bands below 1GHz for Wireless Medical Applications

- SRDs do not share spectrum with high power transmissions (e.g., 433MHz in Europe)
- From an international perspective, bands between 406 and 450MHz are heavily occupied by high power radar, RFID, government, mobile and amateur services
- Bands above 450MHz are best for international harmonization for medical applications
- Canada has proposed to ITU WP1A that consideration be given to developing an ITU-R Recommendation for medical SRD (R07-WP1A-C-121) leading to possible action at WRC-2011 under AI 1.22

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Summary and Conclusion

- MedRadio rules support Low Duty Cycle operation, and are currently harmonized internationally
- Wireless hearing aids will operate near 100% duty cycle
  - MedRadio equipment will suffer premature battery rundown
  - MEDS equipment will suffer significant interference
- Zarlink is in late-stage development of MedRadio chips
  - Substantial investment already sunk (>$40M)
  - Relied on stability of the existing rules
  - Large (>$10M) cost for Zarlink to accommodate any rule change
    10x this for Zarlink's customers
- Viable alternative spectrum for wireless hearing aids exists